

VALUE-BASED PURCHASING FOR PHYSICIANS UNDER MEDICARE

HEARING BEFORE THE SUBCOMMITTEE ON HEALTH OF THE COMMITTEE ON WAYS AND MEANS U.S. HOUSE OF REPRESENTATIVES ONE HUNDRED NINTH CONGRESS

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VALUE-BASED PURCHASING FOR PHYSICIANS UNDER MEDICARE

THURSDAY, JULY 21, 2005

U.S. HOUSE OF REPRESENTATIVES,
COMMITTEE ON WAYS AND MEANS,
SUBCOMMITTEE ON HEALTH,
Washington, DC.

The Subcommittee met, pursuant to notice, at 1:08 p.m., in room 1100, Longworth House Office Building, Hon. Nancy L. Johnson (Chairman of the Subcommittee) presiding.

[The advisory and revised advisory announcing the hearing follow:]

ADVISORY

FROM THE COMMITTEE ON WAYS AND MEANS

SUBCOMMITTEE ON HEALTH

FOR IMMEDIATE RELEASE
July 21, 2005
No. HL-7

CONTACT: (202) 225-3943

Johnson Announces Hearing on Value-Based Purchasing for Physicians Under Medicare

Congresswoman Nancy L. Johnson (R-CT), Chairman, Subcommittee on Health of the Committee on Ways and Means, today announced that the Subcommittee will hold a hearing on reforming physician payments under Medicare by moving to a value-based purchasing program. **The hearing will take place on Thursday, July 21, 2005, in the main Committee hearing room, 1100 Longworth House Office Building, beginning at 10:00 a.m.**

In view of the limited time available to hear witnesses, oral testimony at this hearing will be from invited witnesses only. Witnesses will include the Honorable Mark McClellan, Administrator, Centers for Medicare & Medicaid Services (CMS) and representatives from Medicare provider groups. However, any individual or organization not scheduled for an oral appearance may submit a written statement for consideration by the Committee and for inclusion in the printed record of the hearing.

BACKGROUND:

Physicians and other providers paid under Medicare's physician fee schedule will receive cuts in payment rates of approximately 5 percent annually for the next 7 years, beginning in January 2006. At the same time, Medicare pays providers the same whether they deliver excellent care or care that is ineffective, of poor quality, or out-of-date. Since Medicare pays for resource use, the program and beneficiaries pay for more and more services even when providers deliver ineffective or inefficient care. Congress must continue to examine ways to address these issues within the Medicare program, to stem the tide of rising medical inflation, to prepare for increased enrollment from aging Baby Boomers, and to ensure that the care delivered to Medicare beneficiaries is of high quality.

In recent months, CMS and others have taken steps which provide a basis for transition from a payment system that rewards the delivery of additional services to one that rewards the delivery of quality care. For example, in April CMS began its Physician Group Practice Demonstration, to assess the ability of large physician groups to improve care and create better patient outcomes and efficiencies by implementing care management strategies. In May, the Ambulatory Care Quality Alliance released a starter set of measures of quality and efficiency for use in ambulatory care settings.

In announcing the hearing, Chairman Johnson stated, "For several years, I have argued that the current Medicare payment system for physicians is unsustainable. We have reached the point where we can begin to reward physicians who deliver high quality and efficient care to our seniors under Medicare. This hearing will offer the Subcommittee an opportunity to explore further a repeal of the old formula and implementation of a value-based purchasing program based on the recent work by CMS and others."

FOCUS OF THE HEARING:

The hearing will focus on developments since the last Subcommittee hearing in March on physician payments and value-based purchasing. Witnesses will outline methods to pay for better results in Medicare.

DETAILS FOR SUBMISSION OF WRITTEN COMMENTS:

Please Note: Any person(s) and/or organization(s) wishing to submit for the hearing record must follow the appropriate link on the hearing page of the Committee website and complete the informational forms. From the Committee homepage, <http://waysandmeans.house.gov>, select “109th Congress” from the menu entitled, “Hearing Archives” (<http://waysandmeans.house.gov/Hearings.asp?congress=17>). Select the hearing for which you would like to submit, and click on the link entitled, “Click here to provide a submission for the record.” Once you have followed the online instructions, completing all informational forms and clicking “submit” on the final page, an email will be sent to the address which you supply confirming your interest in providing a submission for the record. You **MUST REPLY** to the email and **ATTACH** your submission as a Word or WordPerfect document, in compliance with the formatting requirements listed below, by close of business Thursday, August 4, 2005. **Finally**, please note that due to the change in House mail policy, the U.S. Capitol Police will refuse sealed-package deliveries to all House Office Buildings. For questions, or if you encounter technical problems, please call (202) 225-1721.

FORMATTING REQUIREMENTS:

The Committee relies on electronic submissions for printing the official hearing record. As always, submissions will be included in the record according to the discretion of the Committee. The Committee will not alter the content of your submission, but we reserve the right to format it according to our guidelines. Any submission provided to the Committee by a witness, any supplementary materials submitted for the printed record, and any written comments in response to a request for written comments must conform to the guidelines listed below. Any submission or supplementary item not in compliance with these guidelines will not be printed, but will be maintained in the Committee files for review and use by the Committee.

1. All submissions and supplementary materials must be provided in Word or WordPerfect format and MUST NOT exceed a total of 10 pages, including attachments. Witnesses and submitters are advised that the Committee relies on electronic submissions for printing the official hearing record.
2. Copies of whole documents submitted as exhibit material will not be accepted for printing. Instead, exhibit material should be referenced and quoted or paraphrased. All exhibit material not meeting these specifications will be maintained in the Committee files for review and use by the Committee.
3. All submissions must include a list of all clients, persons, and/or organizations on whose behalf the witness appears. A supplemental sheet must accompany each submission listing the name, company, address, telephone and fax numbers of each witness.

Note: All Committee advisories and news releases are available on the World Wide Web at <http://waysandmeans.house.gov>.

The Committee seeks to make its facilities accessible to persons with disabilities. If you are in need of special accommodations, please call 202-225-1721 or 202-226-3411 TTD/TTY in advance of the event (four business days notice is requested). Questions with regard to special accommodation needs in general (including availability of Committee materials in alternative formats) may be directed to the Committee as noted above.

* * * **CHANGE IN TIME** * * *

ADVISORY

FROM THE COMMITTEE ON WAYS AND MEANS

SUBCOMMITTEE ON HEALTH

FOR IMMEDIATE RELEASE
July 21, 2005
No. HL-7 Revised

CONTACT: (202) 225-3943

Change in Time for the Hearing on Value-Based Purchasing for Physicians Under Medicare

Congresswoman Nancy L. Johnson (R-CT), Chairman, Subcommittee on Health of the Committee on Ways and Means, today announced that the Subcommittee hearing on reforming physician payments under Medicare by moving to a value-based purchasing program, previously scheduled for 10:00 a.m. on Thursday, July 21, 2005, in the main Committee hearing room, 1100 Longworth House Office Building, **will now be held at 1:00 p.m.**

All other details for the hearing remain the same. (See Health Advisory No. HL-7, dated July 14, 2005).

Chairman JOHNSON OF CONNECTICUT. Good afternoon. The hearing will come to order. Today, we hold our third hearing this Congress on physician reimbursements under Medicare. During our first hearing, experts from the government Accountability Office (GAO) and the Medicare Payment Advisory Commission (MedPAC) and representatives from providers and consumer goods identified problems with the formula used to set payment updates for physicians and other providers paid under Medicare's physician fee schedule. Experts in our second hearing testified about steps that we could take to encourage delivery of high-quality care and use our resources more efficiently and effectively. Today, we will hear about progress that has been made since our last hearing on this subject in March. I am pleased to report that the Centers for Medicare and Medicaid Services (CMS) and physician organizations have made remarkable progress, which lays the groundwork for legislation on value-based purchasing.

Last week Chairman Thomas and I wrote to Dr. McClellan, the CMS administrator here today with us, to ask consideration of administrative changes to the physician payment formula. Specifically, we asked CMS to remove prescription drugs to account for the cost of new and expanded benefits from calculating payment updates. I look forward to Dr. McClellan's response to our letter because I firmly believe that, together, we can address the problems in the Sustainable Growth Rate (SGR) formula. Frankly, if we don't, I believe that we cannot move down the direction that we all believe is productive; that is, a direction that ends up paying for quality.

In May, the Ambulatory Care Quality Alliance identified a starter set of quality and efficiency measures for ambulatory care. This is a critically important first step in developing a value-based purchasing system. The starter set includes 26 measures of care, ranging from prevention measures for cancer screening to chronic condition measures for diabetes, to efficiency measures for overuse of antibiotics in children with upper respiratory infections. While it is a good first step for physicians providing primary care in an ambulatory setting, more needs to be done.

I am encouraged by the collaborative effort of the American Medical Association (AMA), the American College of Physicians, American Academy of Physicians, America's Health Insurance Plans, the National Quality Forum, the Alliance for Specialty Medicine, the National Committee for Quality Assurance, and the many other physician specialty organizations and others who have devoted time and effort to identifying quality and efficiency measures relevant to the care they provide to patients.

While we are not yet ready to collect information on quality and efficiency for all physicians, or to pay based on the reportings or values of those measures, we are much closer than we were only a few months ago. It is an enormous tribute to all the groups I mentioned, all the many involved, and to Dr. McClellan's leadership, that we are all thinking so seriously and deeply about this challenge that faces us. It is time we change the way we pay physicians.

I repeat my call to scrap the SGR formula because it is not only unsustainable, it is irrelevant. Congress should implement a stable annual update based on changes in the cost of providing care. At the same time, we should encourage the use of evidence-based principles to improve health care quality and safety and promote the efficient delivery of care. We should no longer pay providers the same regardless of the quality of care they provide.

Finally, we should require CMS to prepare an annual analysis of the growth in the volume of each of the services paid under the physician service system and provide recommendations for actions to control appropriate growth. I maintain that the SGR system limits our ability and discourages us from looking at sources of growth and judging what is appropriate and what is inappropriate growth. In the real world that faces us, we are going to have to make those judgments more accurately, and we are going to have to be able to understand where we need volume increases in the physician performance areas in order to save costs in the hospital area.

A new value-based purchasing program should include differential payment based on the quality and efficiency of care provided. Measures should be evidence-based, consistent, valid and not overly burdensome to collect; relevant to providers, consumers and purchasers; provide a balanced measure of performance; and include measures of resource use. The system must guarantee fairness by taking into account a patient's health status and willingness to comply with physician orders. It should not directly or indirectly encourage patient selection or deselection.

Finally, it is critical that physicians play an integral role in the development of the clinical care measures. Physician specialty organizations should identify clinical care measures for consideration

by consensus-building organizations, which includes representatives from physicians—and I would say practicing physicians—patients, physician organizations, CMS, and experts in quality and efficiency. The CMS should be required to select clinical care measures from among those recommended by the consensus group. The CMS should also retain authority to identify nonclinical care measures through rulemaking. Our witnesses will expand on these and other issues.

On our first panel we have Dr. Mark McClellan, the CMS administrator. Dr. McClellan will provide us with details about CMS's efforts to fix the physicians' payment update for 2006 and his plans for incorporating value-based purchasing for physician services into Medicare. Our second panel includes Dr. Hedberg from the American College of Physicians and Dr. Armstrong from the AMA, who will describe the extensive work that these organizations have undertaken in this area. In his written testimony, our third witness, Dr. Kassirer, will identify perverse financial incentives in medicine and outline the negative consequences that result. I have been informed that, due to short time available for the preparation of his written testimony, he was unable to include his recommendations for changes to address his concerns. I hope that during his oral presentation and questioning thereafter we will have a chance to hear his recommendations. Dr. Stark—I mean Mr. Stark, would you like to make—I am free and easy with these degrees.

Mr. STARK. I will take the increase in pay, thank you very much. Madam Chair, this is the third hearing we have had in 6 months on physician payments under Medicare. While we have not been able to look at your bill—and nor, as I understand it, has the Administration had a chance, except to read it and then not have it—it is very difficult for us to ask the right questions and make the right statements because we haven't been able to study your bill, which I understand is going to be introduced next week, and that will give us no opportunity to ask reasonable questions today and have decent input. That is generally the way the current leadership in the House has been working; and we, once again, have been precluded from participating in this important topic.

I think the public's interest would be well served if we spent some time, however, on other issues, such as conducting oversight on the confusing Medicare prescription drug benefit. All the hoopla about wanting Democrats to help promote this new law—the word came out this morning that Secretary Leavitt and his merry band are in Chicago right now, and the Chicago Congresspeople were just notified this morning. So, it begs the question whether this is a legitimate effort to inform constituents or a political campaign to sell propaganda to hand-picked crowds. As for today's hearing, I know that pay-for-performance or value-base purchasing—or whatever the current buzzword is—it is the current hot topic. However, I think that we have to consider all aspects of the system to fully understand the perverse incentives that exist today and how, or even whether, they will be affected by the proposed changes in payment policy once we get to look at them.

As for the topic of physician fees, we can't afford to consider the update problem in isolation. For example, even though per-service fees will be reduced under the current law, data shows that the

overall physician spending on a per-beneficiary level will increase because of the greater volume and intensity. I am not saying that successive years of negative 5 percent updates are desirable, but the picture is not as clear as some would have us believe, that doctors are getting more pay per year and that the piecework rate is going down. Maybe they are just doing things better and more quickly. So, we need to pay physicians appropriately to maintain access. I have no problem with physicians making a decent living, even from Medicare, but the evidence on physician income suggests that, although Medicaid reimbursements may be low in some areas, physician incomes continue to rise. The only exception is probably among general practitioners and primary care providers, and I think we all feel somewhat sympathetic to their overwork and underpay.

The current focus on pay-for-performance masks these underlying problems. Value-based purchasing, whatever that is, is not a replacement for SGR. Even if there is some potential for these mechanisms to affect physician practice and ultimately decrease inappropriate volume, this won't occur for decades, and we need a way to control the total cost of physician services today. Past experience with Medicare demonstrates that volume goes up regardless of whether payments are increased or decreased. While some of this increase may very well be appropriate—for instance, more preventative care—data shows time and time again that some is clearly not appropriate. Perhaps it is time to delve more deeply into the underlying payment issues in Medicare with the help of CMS and MedPAC to ensure that we pay appropriately for appropriate care. This is a much less sexy issue, but it is much more real and complex.

There are two more critically important items that ought to be on the table for discussion. Raising physician fees will raise copayments for beneficiaries. Given the record-high premium increases this year and the addition of the part D premiums next year, it seems we should be able to agree that if new money is spent—and I would still argue that this should be budget neutral—budget premiums would be protected—I hope you can agree with me on that—because the beneficiaries will soon use up all their Social Security just to pay their Medicare premium. Second, increasing physician fees exacerbates the problem we will face as a result of the so-called 45 percent trigger. This hidden sword of Damocles is designed to destroy Medicare's entitlement status. Soon we will be chasing our tails over how to clamp down on Medicare general revenue support generated in part by this exercise of the trigger. I hope that we can have an honest conversation about repealing the nonsensical trigger provision sooner rather than later.

I understand what we are doing today is an important issue, but I want to make sure that we have the right pieces in place to ensure volume control before we throw SGR in the trash. I want to protect the beneficiaries from premium increases that could arise from this proposal. I look forward to eventually seeing the bill, if only in the Congressional record, so that we could have an open discussion of how it might be perfected.

Chairman JOHNSON OF CONNECTICUT. Thank you, Mr. Stark. I would remind you that your staff did read the bill, and I think I personally gave it to you last week.

Mr. STARK. No, we have never had a copy. The staff was not allowed to take the bill with them. The same is true of the Administration; they could read it.

Chairman JOHNSON OF CONNECTICUT. Dr. McClellan.

**STATEMENT OF THE HONORABLE MARK MCCLELLAN, M.D.,
ADMINISTRATOR, CENTERS FOR MEDICARE AND MEDICAID
SERVICES**

Dr. MCCLELLAN. Thank you, Madam Chairman, Congressman Stark, all of the distinguished Subcommittee Members. It is a real pleasure to testify with you on value-based purchasing for physicians under Medicare. Paying physicians effectively is one of the most important issues that we face in the Medicare Program, and I am pleased that we are all working on it together. At a time when we are bringing Medicare's benefits up to date, when we have more opportunities than ever to provide up-to-date care to seniors and people with disabilities to help them live longer and better lives, we need to support the participation and leadership of physicians through our payments that take advantage of all these unique opportunities.

We need to ensure that physicians are adequately compensated in Medicare. Medicare's payment system for physicians should support and enable physicians to provide quality care and prevent avoidable health care costs. Physicians are in the best position to know what can work best and improve their practices, and physician expertise, coupled with their strong professional commitment to quality, means that any solution to the problems of health care quality and affordability must involve physician leadership.

The current system of paying physicians is simply not sustainable, as you all noted in your opening statements. Just as 7 years of projected negative updates in physician payments are not sustainable, neither is simply adding larger updates to the current payment system. The current system has resulted in large increases in volume and intensity of services. Some of the resulting expenditure growth reflects valuable improvements in access to innovative medical care, but, as Congressman Stark noted, some of it involves tests and visits and imaging procedures that do not reflect clear medical evidence and that vary widely across medical practices, with no clear relationship to quality of care and outcomes. Despite all the spending growth, physicians often are not getting the support they need to prevent complications and help beneficiaries stay well. CMS is committed to continuing to work with Congress and the medical community to remedy this situation as soon as possible.

One option recommended to CMS to deal with the physician update issue would be to remove part B drugs from the services included in the physician update formula. We are working hard on this issue. Removing drugs, though, presents some difficult legal issues that we haven't yet been able to fully resolve, but, more importantly, it wouldn't solve the entire problem. It should be noted that if we were able to work with physicians to improve care, avoid

duplicative services, and prevent complications just enough to reduce the rate of growth in Medicare spending over 5 years by about 1 percentage point, we would save enough to pay for a physician update of 1.5 percent in all of those years.

Implementing quality measurement and payment systems could reduce the rate of growth, but, more importantly, these steps would also provide better support to physicians to improve quality and avoid unnecessary medical costs for patients and taxpayers. So, I know we can do better. For example, a physician who calls or e-mails a diabetic patient to help them promptly change their insulin doses to keep their blood sugar under control gets no financial support from Medicare, which will pay a lot more if the physician requires the patient to come all the way into the office, even though this approach uses more resources and may lead to worse sugar control. We pay oncologists much more to give patients with metastatic cancer additional chemotherapy drugs, whose use is not guided by evidence-based practice guidance, than we pay to help the patient and their family understand their prognosis and achieve more comfort and a better quality of life, something, again, that the oncologist is in the best position to do. As another example, 21 percent of our beneficiaries who are hospitalized with heart failure are readmitted within 30 days. Studies show that about half of these readmissions are preventable, yet Medicare pays much less when physicians take steps to prevent readmissions.

There are too many examples like these where we pay more when patients have higher costs and worse results. That is because Medicare's current physician payment rates for service are the same regardless of its quality, its impact on improving a patient's health, or its impact on keeping the overall cost of health care down. It is time to provide better support to physicians. Linking a portion of Medicare's payments to clinically valid measures of quality and an effective use of health care resources would give physicians more financial support to take steps that actually result in improvements in the value of care that people with Medicare receive. Madam Chairman, I appreciate your leadership on this critical issue.

In the fiscal year 2006 budget, the President recognized the need for payment reforms to improve the value of care delivered to people with Medicare by building on current Administration efforts to pay for better quality. The MedPAC has also made many recommendations to implement measures of quality and efficiency and to pay for value, and I think it is critically important that physician organizations are helping to lead the way. The AMA has supported the development of quality measures in many specialties, and I particularly want to thank Dr. Armstrong and his colleagues for their time and expertise and collaboration with CMS and other Federal agencies in these efforts.

A number of specialty societies, including the American Academy of Physicians, the American College of Physicians and the Society of Thoracic Surgeons, have helped lead the way in developing clinical quality measures when they proposed specific ways to use them to support better care. Using these quality measures, CMS is now conducting a number of demonstrations and pilots of payment reforms to pay more for better quality, better patient satisfaction

and lower overall health care cost in the Medicare fee-for-service program. These reforms also reflect the experience of private sector payers and health plans that have already implemented the same kind of programs. The CMS has implemented a demonstration project to test pay-for-performance in our fee-for-service payment system for physicians. In our physician group practice demonstration, 10 large multi-specialty physician group practices will continue to be paid on a fee-for-service basis, but they may also get performance-based payments for improving the quality of care and, at the same time, reducing the growth in overall Medicare spending for their patients.

We are seeing, as a result, investments in effective health information technology systems, in patient reminders, in medication assistance, in all the steps that help physicians deliver better care but until now Medicare didn't support financially. The experience in the private sector is even more extensive. The Leapfrog Compendium on Pay-For-Performance includes more than a hundred projects related to physicians. For example, the Bridges to Excellence program, a not-for-profit organization of employers, providers and plans, has three programs to promote and reward improvements in the quality of care for patients, physicians' offices, diabetes care, and cardiac care.

The results of these and many more physician-led initiatives lay a solid foundation for reforming Medicare payments to improve quality and avoid unnecessary costs. In fact, Medicare will shortly implement a pilot program for small physician practices that is based on the Bridges to Excellence program called our Medicare Care Management Performance Demonstration to improve quality and reduce costs and to provide support for implementing effective information technology systems. Madam Chairman, it has taken a lot of collaborative work to get to the point where we can now see the way to a better payment system, to a better alternative, to rapid and costly increases in volume of services on the one hand and the continuing threats of lower payment rates even for high-quality care on the other. It will take more work together to make the transition to a better payment system, that, as you said, it is time to do.

We look forward to working with you and others in Congress and the medical community to develop a system that ensures appropriate payments for physicians while also promoting the highest quality of care without increasing overall Medicare costs. The rapid recent increases in spending make these collaborative efforts even more urgent. We need to increase our emphasis on helping physicians improve quality and avoid unnecessary costs by changing the current physician payment system. Thank you very much for this opportunity, and I would be pleased to answer any of your questions.

[The prepared statement of Dr. McClellan follows:]

Statement of The Honorable Mark McClellan, M.D., Administrator, Centers for Medicare and Medicaid Services, U.S. Department of Health and Human Services

Madam Chairman Johnson, Congressman Stark, distinguished Subcommittee members, thank you for inviting me to testify on value-based purchasing for physicians under Medicare. As you know, the Centers for Medicare & Medicaid Services

(CMS) is actively engaged with both the Congress and physician community on this important topic. Continued improvement of the Medicare program requires the successful participation of physicians and we need to ensure they are adequately compensated for the care they provide to people with Medicare. But how we pay also matters. In addition to providing adequate payments, Medicare's payment system for physicians should encourage and support them to provide quality care and prevent avoidable health care costs. After all, physicians are in the best position to know what can work best to improve their practices, and physician expertise coupled with their strong professional commitment to quality means that any solution to the problems of health care quality and affordability must involve physician leadership.

Because it is critical for CMS payment systems to support better outcomes for our beneficiaries at a lower cost, CMS is working closely and collaboratively with medical professionals and the Congress to consider changes to increase the effectiveness of how Medicare compensates physicians for providing services to Medicare beneficiaries. I am engaging physicians on issues of quality and performance with the goal of supporting the most effective clinical and financial approaches to achieve better health outcomes for people with Medicare. At the same time, however, we are concerned and are closely monitoring the current volume-based payment system for physicians' services, which projects seven years of negative updates in physician payments. Simply adding larger updates into the current payment system would be extremely expensive from a financing standpoint, and would not promote better quality care. Under this system, there are significant variations in resources and in spending growth for the same medical condition in different practices and in different parts of the country, without apparent difference in quality and outcomes. CMS is committed to working with Congress and the medical community to remedy this situation by developing reporting and payment systems that enable us to support and reward quality.

CMS is engaged with a number of stakeholders to address this situation. For example, MedPAC has made many recommendations to improve the payment system. In addition, a number of specialty societies, including the American College of Physicians, American Academy of Family Physicians, and the Society of Thoracic Surgeons, are in the vanguard of leading change. In addition, like many private-sector health care payers and plans, CMS also is conducting a number of demonstrations and piloting various payment reforms to reward providers for better quality, better patient satisfaction, and lower overall health care costs in the Medicare fee-for-service program.

Madam Chairman, in terms of physician payment, the best ideas of physician organizations, health care experts, the private sector, and our own demonstration programs are all pointing to the same conclusion. Medicare needs to move away from a system that pays simply for more services, regardless of their quality or impact on patient health, and consequently contributes to reductions in the physician update under the current payment formulas, to a system that instead encourages and rewards efficiency and high quality care for the Medicare program and its beneficiaries. As it stands, the physician payment system does not always recognize clinically appropriate care. For example, Medicare will pay for a duplicate x-ray or blood test right before surgery if a hospital does not coordinate care adequately with the physician's office. CMS' physician payment system should support, encourage, and provide an incentive for physicians to achieve Medicare savings by avoiding unnecessary services such as duplicate tests and to use those savings in developing improvements to the physician payment system. In addition, the physician payment system also may steer patient care decisions. Oncologists, for example, are paid less for transitioning a terminal patient to palliative care and focusing on quality of life issues than for recommending and providing intensive procedures even if the side effects of those procedures are significant and the benefits negligible. In addition, currently the payment system does not reward physicians who actively prevent readmissions for patients with heart failure or diabetes.

Physician Payments Based on Statutory Formula

Updates to Medicare physician payments are made each year based on a statutory formula established in section 1848(d) of the Social Security Act. The calculation of the Medicare physician fee schedule update utilizes a comparison between target spending for Medicare physicians' services and actual spending. The update is based on both cumulative comparisons of target and actual spending from 1996 to the current year, known as the Sustainable Growth Rate (SGR), as well as year-to-year changes in target and actual spending. The use of SGR targets is intended to control the growth in aggregate Medicare expenditures for physicians' services. Target expenditures for each year are equal to target expenditures from the previous year in-

created by the SGR, a formula specified in the statute comprising the following four factors: (1) the estimated percentage change in fees for physicians' services, (2) the estimated change in the average number of Medicare fee-for-service beneficiaries, (3) the estimated 10-year average annual growth in real gross domestic product (GDP) per capita, and (4) the estimated change in expenditures due to changes in law or regulations.

When actual spending exceeds targeted spending, the following year's update is modified to bring actual spending back in line with the targets. Unfortunately, actual spending has greatly exceeded targeted spending, and the formula results in negative updates to physician payments to correct this disparity. Recent rapid growth in the volume and intensity of physicians' services per beneficiary is driving the growth in Medicare physician spending and resulting in the negative updates. Presently, we project a negative 4.3 percent update to physician payment rates for 2006 and additional negative updates for the following six years. The current system eventually corrects the discrepancy and under our latest projections results in positive updates after 2012. CMS is fully cognizant of the potential implications of seven years of negative physician updates, remains concerned, and is closely monitoring physicians' participation in the Medicare program and beneficiaries access. What is especially concerning is that these reductions in the payment rates for services will occur at the same time as Medicare physician spending continues to go up. Projected increases in the volume and intensity of services for 2006 would result in increases in total physician revenue from Medicare for 2006. In other words, our current payment system has a risk in terms of access problems, yet we still are facing sharply rising increases in Medicare spending.

We need to do better. We will continue to work with Congress and physician communities. Although we have not yet seen evidence of a problem, we are closely monitoring access for people with Medicare. Thus, we need to ensure payment for physicians is adequate and appropriate. Both the President's Budget and the Congressional Budget Resolution presume this will be done in a cost-neutral manner. We have worked with Congress and physicians to understand more about why physician volume, and thus spending, is going up, and to develop better approaches to supporting physicians in providing high quality, up-to-date care.

Volume and Utilization Drive Medicare's Increasing Physician Expenditures

Despite an update to payment rates of 1.5 percent during 2004, preliminary data indicate that overall expenditures for physicians' services during 2004 grew by some 13 percent. Sharp rises in the volume (number) and intensity (type) of services provided to people with Medicare are the driving factors in increasing Medicare's expenditures. Medicare beneficiary growth between 2003 and 2004 and payment modifications required under the Medicare Modernization Act (MMA) account for only a small fraction of total spending growth.

Such a large increase in expenditures has significant ramifications for future Medicare spending, and thus, updates to physician payments. This growth has increased the cost of addressing negative physician updates. These increases strain the Federal budget and contribute to annual increases in beneficiary premiums. That is why understanding the sharp rise in these expenditures in 2004 is very important.

CMS' preliminary analysis of the 2004 increases in spending for physicians' services indicates that major contributors to growth included:

- Increased spending for office visits, with a shift toward longer and more intensive visits;
- Higher utilization of minor procedures such as therapy services;
- Increased number of patients receiving more complex and more frequent imaging services, with notable increases in MRI scans;
- Increased use of laboratory and other tests; and
- Greater utilization of currently covered drugs administered in physicians' offices.

CMS has taken collaborative steps to better understand these concerning trends, including what changes in utilization are likely to be associated with important health improvements and which have limited or questionable health benefits. We have been reviewing the technical aspects of this situation in detail with health policy experts as well as the AMA and various specialty societies. For example, the AMA has provided us with some potential reasons accounting for growth. While it was not possible with available data to precisely analyze the impacts of every factor identified, we were able to assess the impacts of most of them. Generally, our results indicate that while the factors the AMA identified have contributed to higher

spending, our preliminary analysis suggests that these identifiable factors do not account for a substantial part of the \$10 billion spending growth between 2003 and 2004.

In a number of cases, although the rate of spending growth for a particular service may be above average, it is not significantly different than the growth in spending for other, similar procedures where no special clinical developments have yet been identified. For example, the AMA suggested several reasons for a particular increase in the use of echocardiography. However, we compared the growth in these services from 2003 to 2004 with the growth in all imaging services, and found the increases to be the same for both groups (19 percent). Therefore, although the increase in 2004 is large, by itself, the increase in echocardiography services does not account for a disproportionate percentage of the increase in imaging services overall.

For several other services where clinical factors suggested growth might be particularly rapid, we did observe large percentage increases from 2003 to 2004, but the dollar impact was relatively minor. An example is electrical stimulation for bone healing. Spending rose for this service by 35 percent in 2004, but total spending was only \$50 million, although a \$13 million increase from 2003. This factor would have minimal impact in explaining the overall growth in physician spending from 2003 to 2004.

Of the factors the AMA identified, the one that appears to contribute the most to overall spending growth is the drug Pegfilgrastim (Neulasta). Spending for this drug in 2004 was \$518 million, up from approximately \$253 million in 2003. We have not been able to confirm the clinical suggestion that by strengthening the immune system of cancer patients, this drug is preventing immune-related complications so that patients are kept out of the hospital, shifting costs from Medicare Part A to Part B, rather than simply increasing costs. But we remain interested in supporting the development of such "preventive" evidence.

We appreciate the efforts of the AMA and the many specialty societies that assisted CMS in identifying these medical trends. They have helped further our understanding of the reasons for the growth in spending. I am sure that all stakeholders involved in these critical payment issues will benefit from an ongoing, evidenced-based dialogue regarding these issues, particularly focusing on which changes in utilization are likely to be associated with important health improvements and which ones have health benefits that may be more questionable.

Options to Change the Physician Update

The cost of avoiding the negative physician update simply by increasing the update factor is quite substantial. One option suggested by the Medicare Payment Advisory Committee (MedPAC) would legislatively eliminate the SGR system in favor of an update that is similar to the current Medicare Economic Index (MEI), which measures the weighted average price change for various inputs involved with producing physicians' services. CMS actuaries have reexamined the cost of an MEI-based physician update using the recently released mid-session review of the budget. These new budget estimates incorporate the recent experience of substantial volume growth under the current physician payment system. We now estimate the ten-year cost of this approach would be \$183 billion, an increase of \$20 billion from our previous assessment of \$163 billion under the FY 2006 President's Budget Baseline. Earlier this year Congressional Budget Office (CBO) estimated the cost would be approximately \$155 billion. An MEI-based payment update would result in positive updates to physician payments of between two and three percent for each of those ten years.

A second option recommended to CMS would remove prescription drugs from the services included in the SGR, either prospectively or retrospectively. We are currently reviewing the legal arguments regarding whether CMS can take this step under existing authorities, and our actuaries have estimated the payment and budget implications of such changes. A prospective approach would not provide relief to the negative updates projected for 2006 and the succeeding several years. While it would eventually help close the gap between the cumulative target and actual spending, it would not result in positive updates for several years. CMS actuaries estimate this change would cost \$36 billion over ten years using the mid-session baseline.

Some have suggested a retrospective approach that would remove drugs retroactively from the services included in the SGR beginning with 1997, the year the SGR was implemented. Some health care trade associations have asked CMS to make this change administratively, as have members of this Subcommittee, most recently Chairman Johnson and Chairman Thomas. However, retrospective removal presents somewhat more difficult issues of statutory authority than prospective removal. For example, the statute requires the estimated SGR be refined twice based

on actual data. The crux of the issue is that after the SGR has been refined twice, the statute does not provide for additional revisions, which would be required for at least some prior years should drugs be removed from the system retroactively. In terms of budget impact, we estimate that this approach would cost \$111 billion under the Mid-Session Baseline. Moreover, even if the authority existed to remove drugs from the SGR retroactively, positive updates may not occur for physicians in 2006 or the succeeding few years. This is a notable change from estimates using the FY 2006 President's Budget Baseline where the preliminary estimate of the 2006 update would have been positive. The change from a positive to negative update for 2006 is due to higher actual physician spending for 2004 and revisions made to the 2003 data. In addition, prospective or retrospective removal of drugs would increase beneficiary premiums. And because Part B drugs use shows substantial variation across physician practices, payment reforms that provide more support for higher-quality care would probably not ignore drug use, but rather consider how drugs (and other important treatments) are used to lead to better patient outcomes at a lower cost.

It has also been suggested that the SGR be revised to account for National Coverage Determinations (NCDs). The theory is that the spending for NCDs shows up on the expenditure side but the SGR target is not adjusted for them. While coverage of new medical technologies as reflected in NCDs would seem to lead to changes in spending beyond physician control, there has been substantial discussion of this theory in recent years. Much of spending for NCDs is for services covered before the NCD by local carrier discretion. Thus, an NCD does not necessarily increase spending to the extent the local carrier covered the service without an NCD. In many cases, an NCD might simply replace differing local carrier policies with a uniform national policy. In some instances an NCD might limit expenditures if the NCD has narrower criteria than applied previously by local carriers. The use of the real GDP per capita in the SGR formula was intended to be a proxy for a number of factors that might increase the volume and intensity of physicians' services (other than beneficiary enrollment growth and statutory or regulatory changes), including coverage of new services and other factors, whether within an NCD or otherwise. In addition, the NCD impacts are generally small and unlikely to change the physician update significantly. Also, we currently are reviewing the legal arguments on whether CMS can take this step under existing authorities. Nonetheless, CMS will continue to evaluate the evidence related to NCDs and how they are accounted for in physician payments.

CMS will be issuing the proposed physician payment rule for 2006 soon and we welcome comments on these issues and other issues that might affect the physician payment calculations.

Incorporating Performance Based Payments into Medicare

Medicare's current physician payment system pays all physicians equally for a service regardless of its quality, its impact on patient's health, or the efficiency with which services are furnished. Consequently, the current system does not reward physicians when they improve the quality of care, for example, by preventing acute health problems that require expensive hospital admissions or other complications that lead to a greater volume and intensity of services. Many analysts have argued that this may be an explanation for why there are substantial variations across geographic areas and among physicians within areas in the use of services that do not appear to be explained by quality of care or differences in patients treated. That is, the current system often has the effect of directing more resources to care that is not of the highest quality, such as duplicative tests and services and hospital admissions to treat potentially avoidable complications. Conversely, physicians who want to improve quality of care find that Medicare's payment systems often do not provide them with the resources or flexibility needed to do so. As a result, physicians may be discouraged from investing in activities that, properly implemented, have the potential to improve quality and avoid unnecessary medical costs. Linking a portion of Medicare payments to valid measures of quality and effective use of resources would give physicians more direct incentives to implement the innovative ideas and approaches that actually result in improvements in the value of care that people with Medicare receive. We would evaluate the program to assess any savings that might result.

In the FY 2006 budget, the President recognized the potential for payment reforms to improve the value of care delivered to people with Medicare by exploring programs that promote quality in a budget-neutral manner. In its March 2005 Report to Congress, MedPAC offered several recommendations including the development of measures related to the quality and efficiency of care by individual physi-

cians and physician groups. I would like to note that the American College of Physicians is supporting linking physician payment and performance.

CMS is already engaged with the physician community in the development and improvement of specific quality measures. CMS has worked in collaboration with the American Medical Association's Physician Consortium for Performance Improvement and the National Committee for Quality Assurance Ambulatory care to develop measures of improvement in care. This partnership resulted in a set of proposed measures that were submitted late last year for endorsement to the National Quality Forum, a voluntary private consensus setting organization. As part of the Ambulatory Care Quality Alliance (ACA), led by the American Academy of Family Physicians, the American College of Physicians, America's Health Insurance Plans, and the Agency for Healthcare Research and Quality, CMS and other stakeholders, including the American Medical Association and other physician groups, as well as representatives of private sector purchasers and consumers, selected a subset of these measures (26) as a starter set for implementation. Additional measures that assess dimensions of specialty care and efficiency will be added to this starter set. In addition, the ACA is now developing approaches for reporting results to individual patients and physicians and evaluating strategies to minimize physicians' burden of reporting.

The entire starter set of ambulatory care measures are now in the final stages of endorsement. These measures are designed to reflect performance in primary care and also apply to certain specialists, insofar as those specialists are involved in the furnishing of care to patients with common chronic diseases, including diabetes and heart disease. In addition, measures of effectiveness and safety of some surgical care have been developed through collaborative programs like the Surgical Care Improvement Program, which includes the American College of Surgeons. The goal of the Surgical Care Improvement Program is to prevent or decrease surgical complications, in an effort to improve outcomes, and decrease hospital days and unnecessary use of resources. We are also collaborating with many specialty societies, such as the Society of Thoracic Surgeons, to develop quality measures that reflect important aspects of the care of specialists and sub-specialists. For example, we are working closely with oncologists to develop measures of the adequacy of treatment planning and follow-up that oncologists furnish as part of their evaluation and management services; with cardiologists on measures of cardiac care for heart attack or heart failure conditions; and with cardiovascular surgeons on measures related to cardiac surgery. As part of this effort, on July 14, 2005, I sent a letter to a number of specialty societies, summarizing some of the work to date and requesting an update on their efforts to develop quality and performance measures. Historically, CMS has had productive exchanges with most medical specialty organizations, and if an organization has not entered discussions with us, I would encourage them to initiate a dialogue with us as soon as possible so we can work together to develop clinically valid measures and obtain our goal of improving the care we provide the Medicare beneficiaries.

We also are preparing to implement the MedPAC recommendation to use Medicare claims data to measure fee-for-service physicians' resource use and to share these results with physicians confidentially to educate them about how they compare with aggregated peer performance. We are using existing claims data to simulate and test the measurement and quantification of individual physician patterns of practice, incorporating both services they order (including facility services) as well as services they furnish. Resource use is often measured for episodes of care and periods of time (e.g., 3 months). The most widely used measure is total expenditures per episode or period of time. Other measures of resource use are possible, such as examining the percent of a physician's patients who have a particular service ordered. This can indicate potential variations in practice that may affect costs significantly without evidence-based benefits for patients. For example, MRI scans may be ordered for patients with non-specific lower back pain, a condition that often does not warrant the test. By comparing relative use of such a service among physicians, a data-driven foundation for identifying opportunities to avoid some medical costs without harming patients may be developed. As a next step, we expect to begin pilot projects to share the results with physicians confidentially to educate them about how they compare to peers in an effort to decrease the use of unnecessary services.

We also have implemented a number of demonstration projects including one to test pay-for-performance in Medicare's fee-for-service payment system for physicians. The Physician Group Practice demonstration is assessing large physician groups' ability to improve care that could result in better patient outcomes and efficiencies. Ten large (200+ physicians), multi-specialty physician groups in various communities across the nation are participating in the demonstration. These physician groups will continue to be paid on a fee-for-service basis, but they may earn

performance-based payments for implementing care management strategies that anticipate patients' needs, prevent chronic disease complications, avoid hospitalizations, and improve the quality of care. The performance payment will be derived from savings achieved by the physician group and paid out in part based on the quality results, which CMS will assess. Providing performance-based payments to physicians has great potential to improve beneficiary care and ensure fair and appropriate payment in the Medicare program.

In addition, CMS will implement the Medicare Health Care Quality Demonstration. This demonstration program, which was mandated by the MMA, is a five-year program designed to reduce the variation in utilization of health care services by encouraging the use of evidence-based care and best practice guidelines. CMS also is implementing the Medicare Care Management Performance Demonstration, a 3-year pay-for-performance pilot with small and medium sized physician practices that will promote the adoption and use of effective health information technology, i.e., health IT that actually achieves improvements in the quality of care and reductions in preventable costs for chronically ill Medicare beneficiaries. This demonstration will provide performance payments for physicians who meet or exceed performance standards in clinical delivery systems and patient outcomes, and will reflect the special circumstances of smaller practices. This demonstration project will give CMS the opportunity to provide technical assistance to small providers in adopting clinical information technology to improve quality and avoid costs, as CMS has already been working to do in limited pilots. This demonstration, required by the MMA, currently is under development and will be implemented in Arkansas, California, Massachusetts, and Utah. We are supporting an evaluation of this demonstration with AHRQ and insights from health IT implementation that produce improvements in quality and efficiency will be shared broadly through AHRQ's National Resource Center.

Quality Improvement Organizations Assist Physicians' Offices

We recognize that taking advantage of performance-based payment reforms may be more difficult for small providers, rural providers, and providers in underserved areas. Consequently, CMS also has been enhancing its activities to give such providers technical assistance with proven systems improvements and quality improvement initiatives. Beginning August 1 of this year, under our new three-year contract with the QIOs, the QIOs will begin offering assistance to physicians' offices who are seeking to achieve substantial improvements in care through the adoption of health information technology, patient-focused care processes, and clinical measures reporting. In each state, QIOs will use the tools and methods developed in the Doctors Office Quality—Information Technology (DOQ-IT) two-year pilot project to help primary care physicians make changes to improve performance. This initiative is part of CMS's overall commitment to supporting physicians and other providers who are committing to success in our developing programs of public reporting and pay-for-performance.

Over the past year, the CMS California QIO, Lumetra, has been piloting CMS DOQ-IT assistance efforts for over 500 physicians and their offices in California. Many of these physicians' offices are small offices with one or two physicians and are located in rural or underserved areas of California. Lumetra staff and consultants provide consultation and technical assistance for these offices, supporting the clinical process changes resulting from the incorporation of health information technology in their offices, which in turn will allow them to utilize electronic health records, electronic prescribing, decision support and clinical practice guidelines relevant to their patient population, and electronic billing and communications. In addition, QIO staff will assist these offices in implementing office redesign to enhance patient management, and increase office efficiency. All of these efforts are designed to result in enhanced patient safety and better quality of care. Our goal is to help support such effective physician office enhancements becoming standard to all medical practices in the coming years and CMS QIO efforts will help make sure that all physicians' offices can accomplish these enhancements.

The QIOs also have implemented quality improvement projects that lead to better care in rural and underserved areas. For example, Qualis Health, the CMS Alaska QIO, has worked with the almost exclusively rural Alaska providers to increase the rates of preventive services available to rural Alaska residents. Mountain Pacific QIO, the CMS QIO in Hawaii, is working to implement telehealth services to bring care not otherwise available to rural Hawaiian beneficiaries.

Another example of QIO assistance to small physician offices is their assistive role in CMS's release of the VISTA—Office Electronic Health Record Software planned for August 1, 2005. CMS staff has been working with the Department of Veteran's Affairs (VA) staff to develop an inexpensive and interoperable software package

that will allow implementation of a basic electronic health record (EHR) in physician offices. A simplified version of the EHR used in VA Hospitals & Clinics will be stand-alone and allow an in-office EHR that contains computerized medical records, a medication formulary with refill and drug-drug interaction notifications, a reminder system for preventive services and diagnostic tests, and the potential to communicate electronically with other systems in the future. It uses the VA product base which is in the public domain and therefore affordable to small practices taking care of rural and underserved populations. It also is scalable and allows major software developers to devise add-on enhancements. The QIOs will be instrumental in explaining and facilitating the use of this product.

Medicare's Hospital Performance Based Payments Have an Impact

The experience with the MMA provision—paying hospitals an update that is 0.4 percentage points higher if they report data on ten measures of quality—suggests that relatively small payment incentives can have a significant impact on provider behavior. Virtually all hospitals are submitting the required data. There is an increasing belief that linking a portion of Medicare payments to valid measures of quality would support better health care. Any potential approaches to dealing with the physician update would provide a perfect opportunity for such linkage.

Evidence exists that some hospital admissions are preventable. Heart failure patients have a readmission rate of 21 percent over 30 days, yet research shows that about half of the readmissions are preventable. For example, providing angiotensin-converting enzyme inhibitor (ACEI) drugs to heart failure patients is an example of high quality care, yet ACEI prescriptions are found in only 66 percent of audited patient records. Giving beta-blocker drugs to patients with acute myocardial infarction (AMI) can reduce rehospitalizations by 22 percent, but only 21 percent of eligible AMI patients receive a prescription for a beta-blocker. Pneumonia is a very common cause of hospital admissions for Medicare beneficiaries, but many of these cases could be prevented through pneumococcal and influenza vaccinations. Studies have shown that proper adherence to vaccination protocols can reduce hospitalizations for pneumonia and for influenza by about half, with reduced diseases, mortality, and savings for the Medicare Program.

If physicians are supported in their efforts to better manage patient care, preventable and costly hospitalizations, readmissions and admissions for complications may be avoided. CMS' physician payment system should support, encourage, and provide an incentive for physicians to avoid unnecessary services such as preventable admissions.

The Premier Hospital Quality Incentive Demonstration is a demonstration project to test if providing financial incentives to hospitals that demonstrate high quality performance in a number of areas of acute inpatient care will improve patient outcomes and reduce overall costs for Medicare. We believe that creating incentives to promote the use of best practices and highest quality of care will stimulate quality improvement in clinical practice. Under the Premier demonstration, a hospital can receive bonuses in its Medicare payments based on how well it meets the quality measures. Poorly performing hospitals will face financial penalties in the third year.

Preliminary analysis of the demonstration has shown that quality of care has improved significantly in hospitals participating. The demonstration tracks hospital performance on a set of 34 widely-accepted measures of processes and outcomes of care for five common clinical conditions. The 17 measures included in Medicare's national hospital quality reporting program are a subset of these measures. The preliminary analysis shows improvement in all five clinical areas being tracked in the three-year demonstration. The analysis of first-year performance found median quality scores for hospitals improved:

- From 90 percent to 93 percent for patients with acute myocardial infarction (heart attack).
- From 86 percent to 90 percent for patients with coronary artery bypass graft.
- From 64 percent to 76 percent for patients with heart failure.
- From 85 percent to 91 percent for patients with hip and knee replacement.
- From 70 percent to 80 percent for patients with pneumonia.

Overall, these conditions account for a substantial portion of Medicare costs. If we achieve improvements in aspects of care that are proven to help patients avoid complications, patients are less likely to require more costly follow-up care for such conditions, and they are more likely to have a better quality of life. As evidenced by the early work of some of our demonstration projects, we are seeing meaningful results, which are providing a promising foundation to support the most effective clinical and financial approaches to achieve better health outcomes for Medicare beneficiaries.

Private Sector Initiatives Pave the Way for Improved Quality and Efficiency

The private sector also has recognized opportunities to improve quality and efficiency of care through better measurement of the delivery of care in coordination with better reimbursement models. In fact, the Leapfrog Compendium on Pay-For-Performance includes more than 100 projects related to physicians. For example, the Bridges to Excellence (BTE) program, a not-for-profit organization of employers, providers, and plans, has three programs to promote and reward improvements in the quality of patient care for physicians' offices, diabetes care, and cardiac care. To date, participating employers have paid over \$1.65 million in bonus payments to over 800 physicians in the four participating markets for exceeding National Committee for Quality Assurance performance criteria. Results to date indicate that physicians can and do participate and report their performance accurately.

A large health plan in New Hampshire launched a quality improvement incentive program in 1998, rewarding primary care physicians for the provision of quality care. The metrics for its quality improvement incentive program are the Health Plan Employer Data and Information Set (HEDIS) measures. The program uses claims and administrative data from its disease management program to assess physician practice performance. Incentive payments are awarded to practices scoring greater than the network average. In 2001, the average physician bonus payment was \$1,183 and the highest bonus payment was \$15,320. In the first year, the plan's average rates for mammography, immunization, and pediatric exams showed increases. Adult female patients receiving Pap smear tests rose from an overall rate of 80 percent in 1999 to 98.5 percent in 2000 for the top quartile of physician practices. For all performance measures for which 1999 baseline data were available, the average incentive program physician practice conformity with performance measures rose from 51.2 percent to 65.6 percent in 2000.

In 2003 a large health plan in Massachusetts launched a group practice incentive program for groups of specialists. Group practices are measured in three categories: patient satisfaction and access, quality of care, and cost. Group practices that perform better than average on the quality measures earn a bonus that could total up to fifteen percent of the regular fees paid to that physician group.

An Illinois coalition of employers initiated a program in 2000 that provides incentives to physicians for monitoring diabetes patients. Compensation is awarded to physicians in the program who meet annual goals in diabetic treatment thresholds. To gain physician buy-in into the program, a committee of physicians developed the performance goals. The coalition and medical group administrators negotiated the amount of the financial incentives a medical group could receive if they met the goals. Results reveal that diabetic care for patients in the program is significantly better than state averages and cost trends for diabetics are better than trends for all other conditions.

A Hawaiian medical association launched a voluntary practitioner quality and service recognition program. Practitioners who enroll share in a multimillion dollar budget earmarked to recognize practitioners for adhering to recognized standards of quality and clinical practices proven by research to improve clinical outcomes. Each program participant receives an award based on his or her scoring in each of the program components—quality indicators, patient satisfaction, and business operations. Practitioners are measured on a total of 68 clinical measures. Analysis of data on key clinical quality indicators over the six years of the program demonstrates statistically significant improved performance.

In Minnesota a health partner's program recognizing outcomes offers annual bonus awards to primary care clinics that achieve superior results in effectively promoting health and preventing disease. Eligible primary care groups are annually allocated a pool of bonus dollars that is awarded if a group reaches specific comprehensive performance targets. Since 1997, bonus awards have totaled over \$2.5 million. The impact on quality of care has been substantial. The proportion of diabetes patients meeting optimal care standards nearly tripled since 1999, and the rates of optimal coronary artery disease patients reaching all treatment targets doubled. The rate of members receiving all preventive care doubled. Tobacco use assessment at all visits increased from 45 percent to 85 percent over four years and more patients are routinely provided assistance to quit. Diabetes eye and kidney complications rates dropped by nearly 50 percent, and costs are trending significantly below costs for all other patients. Tobacco use rates dropped ten percent to an all time low. In Minnesota death from heart disease dropped to the lowest rate in the nation and continues to decline.

A health care leadership association of health plans, physician groups, and health systems in California recently implemented coordinated, state-wide pay-for-performance initiatives. Based on a comparison of data from the first year (2003) and test

year (2002) nearly 150,000 more California women received cervical cancer screenings, 35,000 more California women received breast cancer screenings, 10,000 additional California children received two needed immunizations, and 18,000 more Californians received a diabetes test. The program paid an estimated \$50 million to 215 California physician groups in the pay-for-performance program in 2003 (paid out in 2004), and an estimated total of \$100 million to the same physician groups under all of the association's quality programs.

The American Society of Clinical Oncology's Quality Oncology Practice Initiative (QOPI) is an oncologist-led, practice-based quality improvement initiative. QOPI's goal is to promote excellence in cancer care by helping practices create a culture of self-examination and improvement. The process employed for improving cancer care includes measurement, feedback, and improvement tools for medical oncology practices. Practicing oncologists and quality experts developed the QOPI quality measures, which are derived from clinical guidelines or published standards, adapted from the National Initiative on Cancer Care Quality (NCCCQ), or consensus-based and clinically relevant. Although the measures not linked to financial reimbursement yet, QOPI is an example of a specialty society-driven quality initiative that can be easily linked to a pay-for-performance program.

Results of these and many more physician-led initiatives lay a sound foundation for CMS to move forward collaboratively with you and with leading physician and health professional organizations with performance based payments for physicians in Medicare to improve quality and efficiency. These approaches also are aligned with emerging requirements from medical specialty boards for maintenance of certification. While recertification has traditionally involved demonstrating cognitive knowledge only, all boards are moving to link maintenance of specialty certification with demonstrated efforts to improve clinical care quality and performance. We recognize that physicians need to be actively engaged in establishing this new direction and will continue close consultation and collaboration to assure improved quality and reduced burden for busy practitioners.

Conclusion

Madam Chairman, thank you again for this opportunity to testify on improving how Medicare pays for physicians' services. We look forward to working with Congress and the medical community to develop a system that ensures appropriate payments for physicians while also promoting the highest quality of care, without increasing overall Medicare costs. The rapid increases in physician spending in 2004 make these collaborative efforts even more urgent: we must assure both access to high-quality care and fiscal sustainability. As a growing number of stakeholders now agree, we must increase our emphasis on payment based on improving quality and avoiding unnecessary costs to solve the problems with the current physician payment system. I would be happy to answer any of your questions.

Chairman JOHNSON OF CONNECTICUT. Thank you, Dr. McClellan. I was interested in the statement in your testimony, which I didn't see in your written testimony, that if you reduce one physician services use by 1 percent—now is that across the definition of physician services under SGR?

Dr. MCCLELLAN. Well, that is overall Medicare services. In our discussions with a lot of the medical groups, they have pointed out a lot of steps they could take to help reduce costs in other parts of the Medicare program, for example, by avoiding hospitalizations, by avoiding expensive surgical procedures, and steps like that. So, if we can find ways to work with physicians to support them in those activities, we can get the overall cost down; that, in turn, can help give physicians a more stable payment system.

Chairman JOHNSON OF CONNECTICUT. It also means that we have to be able to see "savings" as money saved in part A by actions taken in part B.

Dr. MCCLELLAN. That is right, and that is why understanding the connections between steps that physicians can take and the impact on overall costs is so important. Congressman Stark men-

tioned that. We have been doing a lot of work to understand that better, with help from the AMA and other societies, and I think we are in a much better position to move forward in that direction.

Chairman JOHNSON OF CONNECTICUT. One of the problems is that many of the things that you need doctors to do—and you give a number of examples in your testimony—increases office expenses. It means they are seeing people to provide preventive drugs. They are seeing people to provide preventive advice and so on and so forth. Once they get someone in with an early sign, there might be other tests. So, there is a lot of ways in which front-loading the care to keep people out of hospitals and emergency rooms actually increases services; and under the SGR, that decreases physicians pay, does it not?

Dr. MCCLELLAN. That is correct.

Chairman JOHNSON OF CONNECTICUT. How can you possibly provide incentive payments when 5 percent cuts are going to wipe out any incentive payment, certainly even any positive payment?

Dr. MCCLELLAN. I agree that the current system with its forecast of 7 years of close to 5 percent payment cuts is just not sustainable. At the same time, while many of these services that physicians are providing in their offices more frequently are going to help patients live longer and better lives, when you look at the actual details, some of the services—again, as Congressman Stark mentioned—do not appear to be related to new medical evidence or new breakthroughs in medical technology. It is things like patients seeing specialists four or five times in 3 months, rather than just once.

Chairman JOHNSON OF CONNECTICUT. I appreciate that, but not only is the SGR not sustainable, there isn't any way you can make any progress on payment-for-performance as long as the SGR formula is in place in the law; isn't that true?

Dr. MCCLELLAN. We would certainly be in better shape under a different approach, and that is what we are seeing in some of our—

Chairman JOHNSON OF CONNECTICUT. Wait a minute now. Not only would you be in worse shape, you would also have negative updates even if you add benefit-for-performance under the current formula; isn't that true?

Dr. MCCLELLAN. That is right. Under the current formula, the big increase that we see in utilization creates this vicious cycle of automatic reductions and payment cuts, and you get into that problem.

Chairman JOHNSON OF CONNECTICUT. Big increases in utilization, as was made very clear in the letter from your office to MedPAC, have a number of components to it since we pay lots of other people, besides physicians, under this part of the law. So, as long as we are responsible for evaluating growth of services in those areas and managing that, we are in as strong a position under repeal of SGR as we are currently. In fact, we may be stronger because you will get a clear identification of growth of costs and services in each one of those areas, isn't that so? If you structure the loss so that—

Dr. MCCLELLAN. I do. I also think, though, that the decisions, as I said in my opening statement, the decisions that physicians make matter; and there are lots of things that every doctor that I talk to around the country can do. These are things that I know from my own medical practice, that if we had a system that supported quality care rather than just more volume, regardless of its impact on patients' health, could help physicians provide more of those services. Those could have an impact on reducing all types of other costs, not just the costs in their own offices.

Chairman JOHNSON OF CONNECTICUT. I absolutely agree with you, but I don't see how we shift to that system under the current law, because the current law will defeat us before we even get started. Certainly its plan of defeat is so many years that, unless we do something about it, we can't proceed down this new path, which will both improve quality and control costs. We all agree it will control costs. So, I want to make sure that it is clear and understood between us and everyone in the room that you cannot do this unless you change current law.

Dr. MCCLELLAN. That is why we are here today. That is why we are working so closely with all the Committees of jurisdiction. That is why we are working so closely with the medical associations on this very important priority.

Chairman JOHNSON OF CONNECTICUT. Now, a lot of examples have been given to me. If we repeal the law—I suppose this would be irrelevant—but the law requires that we adjust SGR for law and regulation. Now, there are a lot of program memorandums and a lot of national coverage decisions that have the effect of increasing the cost under Part B.

In some of the later testimony, a lot of things are laid out effective January 1. This is from the AMA's testimony: The following new or expanded Medicare benefits, some of which have been mandated by AMA, will be required: the physical examination, diabetes screening, cardiovascular screening, blood tests—it goes on through quite a long list.

It is also true that we have had national coverage decisions that required that we cover PET scans for Alzheimer's. That ailment involves a doctor's office visit, carotid artery study, smoking cessation and many other things, photodynamic therapy for macular degeneration. It is impossible to cover these things without there being an increase in office visits. So, those are not excluded from the SGR, and so they are also part of what is causing the apparent need to cut physician payments. In that 13-percent increase, I think 4.4 percent is office-based.

So, what I am getting at is, there are a lot of factors here that the current payment system sort of obscures in terms of our taking responsibility for controlling them. I think pay-for-performance will not only enable us to save money and improve quality, but it will also enable us to get at the causes of some of the growth in Medicare spending. We can't do it unless we make changes to the SGR formula, either of dramatic dimensions or repealing altogether; and we can't repeal it altogether without some pretty serious collaborative efforts.

Dr. MCCLELLAN. Again, we are pleased to collaborate on this. I can think of no issue more important than getting this right. It

is so important for quality and so important for access of care and so important for avoiding unnecessary costs in the Medicare Program.

Chairman JOHNSON OF CONNECTICUT. Thank you. I am going to yield to Mr. Stark, but I do want to conclude by reminding us that, if we don't repeal the current law, we can't proceed down this road. Mr. Stark.

Mr. STARK. Thank you, Madam Chair. Dr. McClellan, let's go down this road a minute. Let's pretend for a minute that you are Dr. Walsh. You are a urologist. Would you operate on a patient's prostate before you took an x-ray?

Dr. MCCLELLAN. Again, the required medical standards for care depend on the specific circumstances, but I would sure want to follow the best available evidence, and generally that means getting it beforehand.

Mr. STARK. What I am getting at—

Dr. MCCLELLAN. Should I start referring to you as Dr. Stark? [Laughter]

Mr. STARK. You now have a series, as you have mentioned in your testimony, of demonstrations; and it always seems to me that, where we are not physicians here, and don't know anything about the practice of medicine, that we ought to defer to those who do—and neither do anybody on our staffs know anything about the practice of medicine.

You have some demonstrations going on where you have 200 physicians in 10 large practices, some of the primary ones around the country, including the Middlesex Health System in Connecticut, and a variety of premier group practices. You have another practice—another demonstration that is smaller and medium-size physician practices, fee-for-service docs; and you have another one that deals with the improvement of care. Don't you suspect that we may learn something from those demonstrations that would help us craft a better program to be used universally?

Dr. MCCLELLAN. I do. That is the reason for undertaking these programs that go across the spectrum of different types of physician practices and—

Mr. STARK. Now we know, also, that although it is not a big part of Medicare, what, 20 percent of our Medicare beneficiaries are in managed care plus or HMOs or some kind of managed care program; is that about right?

Dr. MCCLELLAN. That is about right, yes, close to 20 percent.

Mr. STARK. The MedPAC recommended to us—I don't know if they recommended to you, but they recommended to us that any program of this type really ought to start with managed care plans for a variety of reasons. First, they claim, for the most part, that this is what they are doing. The managed care guys came to us and said we want a bonus because we do all these things as part of our program. Second, they have the data, whether the group is valid or not statistically. If you use a group of managed care plans—we are paying them right now about 115 percent of what we would pay fee-for-service docs, why not start—if we are going to implement something before your demonstrations are finished—and we have to. Yours may take a couple of years. Why not start with this group where we can get kind of instant response, if you will, from those

who say that is what they are doing and where we could observe easily and not get a lot of push-back from solo practitioners in Susanville, California, who say, geez, I am up here 50 miles away from anyplace and you are impacting my practice. What would be wrong with following MedPAC's idea and starting much more quickly with our managed care providers under Medicare?

Dr. MCCLELLAN. Well, I think we should be focusing on improving quality and avoiding unnecessary costs across the board; and that goes for Medicare advantage plans, too.

Mr. STARK. Well, that wasn't my question.

Dr. MCCLELLAN. Well, that is why we have implemented some of the changes already. Just to get to the full answer of your question, you are absolutely right, these plans are offering additional benefits. People can save about a hundred dollars a month now. They are more widely available than ever before as a result of the payment reforms. What the payment reforms did was put in place a system of competitive bidding. So—

Mr. STARK. Then why not start with these guys in terms of the quality requirements and the study of what they yield?

Dr. MCCLELLAN. Well, the plans report quality measures now, and they also get paid based on their bid. There is not a regulated price that Medicare pays each Medicare management—

Mr. STARK. You require the minimum benefits that they have got to provide—we do.

Dr. MCCLELLAN. Right. We also require—

Mr. STARK. Why can't we, therefore, require the standards that we are discussing today? They more or less say what it is they are doing.

Dr. MCCLELLAN. There certainly is a lot of interest in that, and we are absolutely willing to look at it. I am just saying the reason that that is a little bit different is because there is not a Medicare regulated price there. We pay a set amount for every physician service set by statutes that—

Mr. STARK. Let's deal with quality first and price second. Let's just presume that the most important thing for us is quality, and we could find out more quickly because we have a universe that must respond—regardless, really, of what we pay them—to the benefits that we prescribe they must provide. Then they can bid among themselves for these base benefits.

If you want to say that, for a diabetic, certain tests have to be done periodically, you could require that of every managed care plan. It would be an argument of whether you have got to pay them more for that or not, but you could immediately get 20 percent of your beneficiaries, our beneficiaries, covered. As I said, you have already got plans. You say, if that is what they do, let's make them put their practice where their mouth is and say, okay, if that is what you do, we are going to add that requirement, we are going to study the outcome.

We would be able to get going more quickly with people who have submitted to us that that is why they are better, and they are submitting that to the patients as well—I mean, to the beneficiaries. I do suspect we are going to get push-back, unless we pay them a lot, from a lot of sole practitioners. You say, let's start with

the guys who we have the availability to change the way they practice already.

Dr. MCCLELLAN. I think what you are saying is, why don't we—if we know what good care is, why don't we only pay if we get the good care?

Mr. STARK. I am for that.

Dr. MCCLELLAN. Well, the performance-based payments are a step in that direction. It doesn't go all the way that far because there may be exceptions; some patients may be difficult, or the measures may not be perfect. There are other things that we don't measure that we also want to support, but the performance-based payments are certainly moving in that direction. One hundred percent of the payment is not determined by quality, but at least a few percentage points are. I think there is strong interest in moving in that direction.

Chairman JOHNSON OF CONNECTICUT. Let me just add to this discussion before I recognize Mr. Hayworth, because I think it is terribly relevant to my colleague from California's question and didn't come out in the answer. We did change the law in regard to the plans in the Medicare Modernization Act (P.L. 108–173). We actually mandated that they must do disease management, and a lot of these quality protocols are associated with the management of chronic illnesses.

Mr. STARK. All I am suggesting, Madam Chair, is, even the ones you suggest, we could mandate on the plans, because we are dealing with, as I said, a group that has a minimum standard that they have to provide.

Chairman JOHNSON OF CONNECTICUT. First of all, the likelihood is that they are not only doing that and a lot more. When we developed these standards, we looked at the 29 standards around which consensus had been built; they are pretty minimal, and most of the plans in the private sector are well ahead of that. It is hard to hold the fee-for-service system accountable in the same way because you don't have the offsets that you have in the whole plan. The whole plan can pay for it. That is just the one other comment that I would make, is that in all your pilots you have a source of cross-subsidy, because they are either very big special physician groups or they involve plans that also have hospital reimbursement responsibilities. So, they can pay for the pay-for-performance and come out saving money. That is the problem with the individual physician.

Dr. MCCLELLAN. The Medicare Care Management Demonstration, one of the new ones that we are starting soon is for special small companies. We are doing it in California—

Chairman JOHNSON OF CONNECTICUT. We will come back to that, because you should talk about budget neutrality in that regard. Mr. Hayworth.

Mr. HAYWORTH. Thank you, Madam Chairman. Dr. McClellan, welcome; good to see you again. It is my understanding that CMS defines physician services to include prescription drugs when calculating the payment update, but does not include prescription drugs in the definition of physician services anywhere else. Why the different treatment?

Dr. MCCLELLAN. Well, Congressman, this stems in part from the statute. There are two different definitions of physician services. One is for payment rates under the physician fee schedule and the other is for services that are covered under the SGR formula, this automatic update formula that we have been talking about. In fact, the statutory language is that the SGR has to include "other items and services that are commonly performed or furnished by physicians or in a physician's office." So, that is the reason why I think the historical read has been that the SGR should include things like laboratory tests and drugs and minor procedures, even ones the physician doesn't perform himself or herself; and the thought before the SGR, as Congressman Stark mentioned earlier, is that physicians have a role in ordering or furnishing these services.

Now, we are in the process of looking again at our statutory authority for a possible different definition that wouldn't include drugs, but that is the kind of thing that we have to overcome to get there. There are a lot of really smart lawyers working on this, and I hope they are going to be able to get to a good and appropriate conclusion.

Mr. HAYWORTH. When lawyers meet doctors, we face interesting challenges in public policy. It really is, when you think—I guess the old expression was "from soup to nuts"—but we think about how medical care has advanced since 1965, the various permutations we have tried to provide legislatively to update Medicare 40 years later, and it is an unenviable task upon which we collaborate. In that spirit, one other interrogative. Will CMS have measures to assess the quality of care delivered by each specialty and subspecialty of physicians in Medicare in 2006?

Dr. MCCLELLAN. That is absolutely our goal. I would emphasize that this is not a CMS activity, this is an activity that is led in many cases—and certainly participated in all effective cases—by the specialty societies. In a recent response to a request for information on this topic from Chairman Thomas and Chairwoman Johnson, I wrote back and provided a list—and I would be happy to provide that to you—of all the work that has been completed or is in progress among the specialties.

[The information follows:]

Department of Health & Human Services
Centers for Medicare & Medicaid Services
Washington, D.C. 20201

Hon. William M. Thomas
Chairman, Committee on Ways and Means
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

Thank you for your letter in which you seek our assistance in moving the Medicare Program toward value-based purchasing. We share your goal of providing payments that help reshape the way we deliver health care in this country to provide better support for greater quality and fewer unnecessary costs, and improved health. We are committed to working with the Congress, the provider community, and other stakeholders to develop reporting and payment systems that enable us to support and reward quality.

At present, the Medicare Program uses eleven different fee schedules or prospective payment systems to pay claims for services from over one million health care providers. As you mentioned, these fee-for-service payment systems pay physicians

and other health care providers based on the number and complexity of services provided to beneficiaries, regardless of their quality, efficiency, or impact on health outcomes.

As a result, our payment systems often have the effect of directing more resources to delivering care that is not of the highest quality, such as duplicative tests and services, as well as hospital admissions or visits to treat potentially avoidable complications. Conversely, providers who have good ideas and want to take action to improve quality of care find that Medicare's payment systems do not provide them with the resources or the flexibility needed to do so. As a result, providers are unable to invest in activities that, properly implemented, have the potential to improve quality and avoid unnecessary medical costs. Such activities could include patient help lines, health information technology (HIT) systems that help patients with chronic diseases understand how they can prevent complications that result in costly hospitalizations and doctor visits, or reminder systems for using preventive services. Linking a portion of Medicare payments to valid measure of quality and effective use of resources would give providers more direct incentives and financial support to implement the innovative ideas and approaches that actually result in improvements in the value of care that our beneficiaries receive.

In his FY 2006 Budget, the President recognized the need for payment reforms to improve the value of care delivered to Medicare beneficiaries. Such reforms would build on the action the Administration has already taken to promote quality by using data from Medicare providers to construct publicly available measures. The Medicare Payment Advisory Commission (MedPAC) also offered several recommendations in its March 2005 Report to Congress to promote value-based purchasing. We generally support MedPAC's goals in this area, and we are working actively with many outside organizations, particularly in provider-led efforts, to achieve higher quality and better use of resources.

Please find below summary responses to each of the questions you raised in your recent letter. Where applicable, we have also attached additional, more detailed material.

Development of Quality Indicators. The foundation of effective pay-for-performance initiatives is collaboration with providers and other stakeholders, to ensure that valid quality measures are used, that providers are not being pulled in conflicting directions, and that providers have support for achieving actual improvement. Consequently, to develop and implement these initiatives, CMS is collaborating with a wide range of health care providers, other public agencies, and private organizations who share our goal of improving quality and avoiding unnecessary health care costs. Enclosure 1 provides more detail about our efforts to work with hospitals, skilled nursing facilities, home health agencies, end-stage renal disease (ESRD) facilities, and physicians to develop measures.

The healthcare community has already exhibited leadership and interest in quality measurement, public reporting, and paying for performance. We have heard repeatedly from individual providers and provider organizations around the country about their desire to support the development and implementation of appropriate measures and payment methods and to participate in well-designed initiatives in this area. We will continue to work with health care providers and Medicare beneficiaries to make further progress on these efforts.

To date, we have worked with the Hospital Quality Alliance (HQA) in the selection of a starter set of often consensus-derived hospital performance measures for public reporting. Consensus around these measures was achieved because these measures are widely viewed as meaningful elements of quality, they are clinically valid, and they are feasible and not too costly to collect. These are the same measures that were established under section 1886(b)(3)(B)(vii)(II) of the Social Security Act, as added by section 501 (b) of the Medicare Modernization Act (MMA). It is important to note that most hospitals are already reporting a larger set of clinical quality measures than were required by the MMA, and that we expect to expand these measures further in the coming year to include standardized measures of quality from the beneficiary's perspective and outcome measures, such as those related to post-surgical complications.

CMS has also been working closely with consumer groups and nursing home leaders through the Nursing Home Quality Initiative, a collaborative effort to improve quality of care in nursing homes. A key element of this effort is the development and improvement of specific quality measures. Currently, we publicly report 15 measures of nursing home services that are submitted by facilities via the Minimum Data Set (MDS). The quality measures were endorsed by the consensus process of the National Quality Forum (NQF). The nursing home industry, patient advocacy groups, and other stakeholders are working with LIS to improve these measures, while we build a more robust set of measures. For example, in our recent proposed

rule for payment of skilled nursing facilities, we sought comment on additional quality measures and the design of incentives for superior performance. In fact, we are collaborating to assess and develop possible pay-for-performance models, and have recently contracted with Abt Associates to develop a potential demonstration project in this area.

CMS has also been collaborating with provider groups and other stakeholders involved in home health care and care for patients with end-stage renal disease. In the home health care setting, CMS now receives quality data regarding the status of a patient's physical and mental health, maintenance or improvement in the patient's ability to perform basic daily activities, and patient medical emergencies. The home health measures are based on information collected on Medicare or Medicaid patients who receive care at a Medicare certified home health agency. For dialysis facilities, CMS's Clinical Performance Measures (CPM) Project currently monitors 16 quality measures that report the quality of dialysis services in three areas: the adequacy of hemodialysis and peritoneal dialysis; anemia management; and vascular access management. In addition, CMS currently collects data on patient nutrition, and is developing additional measures related to kidney transplant referral and end stage renal disease bone metabolism.

We have also made substantial progress with physician groups and other stakeholders on the development and use of measures for physician-related services. Measures of the quality of ambulatory care have been identified through collaboration between CMS, the American Medical Association's Physician Consortium for Performance Improvement and the National Committee for Quality Assurance (NCQA). This collaboration resulted in a set of proposed measures that are currently being considered for endorsement by the NQF. As part of the Ambulatory care Quality Alliance (AQA), CMS and other stakeholders, including the American College of Physicians, the American Academy of Family Practice, and other physician groups, as well as representatives of private health plans, selected a subset of these measures as a starter set for implementation. These measures cover diabetes, heart disease, asthma, and preventive screening. These measures are already in use in an ongoing Medicare demonstration project.

The entire starter set of ambulatory care measures are now in the final stages of endorsement. These measures are designed to reflect performance in primary care and may also apply to some specialists as well, insofar as specialists are involved in the furnishing of primary care to patients with common chronic diseases, including diabetes and heart disease. In addition, measures of effectiveness and safety of some surgical care have been developed through collaborative programs like the Surgical Care Improvement Program, which includes the American College of Surgeons. We are also collaborating with many specialty societies to develop quality measures that reflect important aspects of the care of specialists and sub-specialists. For example, we are working closely with oncologists to develop measures of the adequacy of treatment planning and follow-up that oncologists furnish as part of their evaluation and management services; with cardiologists on measures of cardiac care for heart attack or heart failure conditions; and with cardiovascular surgeons on measures related to cardiac surgery.

While these collaborative processes have already resulted in clinically valid quality measures for many physician specialties, some specialty societies report that they are still in the development stage, and a few are not reporting any activity. The progress of many specialties to date clearly indicates broad interest from CMS and other key stakeholders and consensus groups like the

NQF, to support the efforts of specialty societies to develop and refine their measures. As we have indicated, we are pleased to work with any medical specialty to support their quality measurement and improvement efforts. Enclosure 2 provides a list by specialty of the types of quality measures that have been developed or are under development. A preliminary assessment indicates that the specialties for which some measures have been developed account for about half of Medicare physician spending. Specialties accounting for another 40 percent of physician spending have measures under development.

In addition, virtually all specialties have noted that evidence-based guidelines for best practices have been developed for many important aspects of the care they provide. Such guidelines do not apply to all patients receiving care from a particular specialty, but they do generally reflect the state of medical evidence about what works best in the specialty for many of the common problems they treat. Some have suggested that, while they work to develop more specific clinical quality measures, a useful interim indicator is physician reporting on whether a relevant practice guideline was followed for the care of a patient (and possibly, a reason for not following a relevant guideline). A number of private-sector efforts are implementing such approaches now with the goal of improving quality, with some promising re-

sults. Such data also help identify circumstances where better medical evidence is needed to help improve practices, another key step for achieving quality improvement. In addition, there is some evidence that compliance with such guidelines may lead not only to better quality but also to better use of resources.

We are exploring methods of reporting physician quality measures through claims and other methods. Many measures with clinical aspects can be reported through existing data systems. For example, in the current oncology demonstration project, physicians are assessing the symptoms of Medicare beneficiaries who are receiving chemotherapy using validated, widely accepted symptom questionnaires that focus on nausea and vomiting, pain, and fatigue. The physicians participating in the demonstration project report on the patients' symptoms via the existing Medicare claims system. Such a reporting mechanism could potentially be used for other specialties, whether for reporting patient symptoms, or for reporting on evidence-based practices that enhance the quality of care.

Systems for Reporting and Analyzing Quality Indicators. Implementing measures in a pay-for-performance system will require infrastructure that can obtain appropriate information from providers, store and aggregate it as necessary, and prepare it for use in payment systems. Over the past few years, CMS has developed an infrastructure that can serve to collect data for quality measurement purposes via secure channels for its submission, storage, analysis, validation, and reporting. The consistent construction and analysis of hospital quality measures based on reported quality data from 11early all hospitals illustrates the key aspects of such systems. Similar tools can be applied in other settings, such as ambulatory care.

To submit data on quality measures, hospitals employ either Joint Commission on Accreditation of Health care Organizations (JCAHO) Performance Measurement System vendors or the CMS Abstraction and Reporting Tool (CART). CART is a broadly applicable software tool that providers and their designees can use to abstract clinical data needed for quality measures from medical records. This tool was designed and developed by CMS with input from JCAHO and the Quality Improvement Organizations.

CMS has also developed a system for secure, HIPAA-compliant transmission of clinical quality data on hospital care for the consistent construction and validation of quality measures. Hospital data is submitted via QNet Exchange—the CMS-approved electronic system for secure communications and data exchange—to a national data repository for private healthcare data. Currently this repository contains information on the ten measures collected pursuant to section 501 (b) of the MMA plus the growing number of additional measures collected under the Hospital Quality Alliance Initiative. Data can be submitted at any time throughout the year, but there is a deadline for submission of each quarter's hospital discharges.

After the data are received in a valid format, the measures are calculated by editing the data against appropriate logic to assure valid measure development. This logic, specified by a diverse group of Federal and non-government clinical experts, includes medical procedure and condition codes, exclusion criteria, and other empirically based measure-specific rules. Data submitted by hospitals are also validated through independent abstraction of medical records by a CMS contractor, the Clinical Data Abstraction Center. Hospitals have an opportunity to review the results for 30 days before they are posted.

Size of Incentives Needed to Encourage Reporting. The experience with section 501(b) of the MMA and other programs suggests that limited adjustments in payment rates may be sufficient incentive to encourage providers to perform well on measured aspects of performance. section 1886(b)(3)(B)(vii)(II) of the Social Security Act, which was added by section 501(b) of the MMA, requires a 0.4 percentage point higher payment update for acute care hospitals that submit information on ten measures of quality for each of fiscal years 2005, 2006, and 2007. If a hospital provides the information by a specific date in the prior year, the full update applies to all inpatient discharges from that hospital during a subsequent fiscal year. Nearly every eligible hospital in the country was willing and able to submit the required data in order to qualify for full update—a clear indication that well-defined incentives can bring about appropriate system change.

Further, CMS has partnered with Premier Inc., a nationwide alliance of not-for-profit hospitals, to conduct a demonstration program designed to improve the quality of inpatient care for Medicare beneficiaries by providing financial incentives. Payment adjustments under the demonstration will be provided to hospitals scoring in the top 20 percent for a given set of quality measures—an additional 2 percent on top of the normal DRO payment will be made to hospitals scoring in the top 10 percent, and an additional 1 percent payment will be made to hospitals in the next highest 10 percent. In the third year of the demonstration, hospitals that do not achieve significant absolute improvements above the demonstration baseline will be

subject to reductions in payments. Preliminary results released in May show that these modest payment adjustments are sufficient to drive quality improvement. This project further validates the fact that payment incentives are bringing about real, meaningful change. We are encouraged by these early results and are using this effort to begin laying the foundation for a pay for quality program for all hospitals.

The Physician Group Practice Demonstration project presents another example. This project is designed to test pay-for-performance in Medicare's fee-for-service payment system for physicians. The project is assessing the ability of large, multi-specialty physician groups to improve care that could result in better patient outcomes and efficiencies. Participating physician groups will continue to be paid on a fee-for-service basis, but they are earning performance-based payments of up to several percent (up to 5 percent of their performance target) for implementing care management strategies that anticipate patients' needs, prevent chronic disease complications, avoid hospitalizations, and improve the quality of care. The performance payment will be derived from savings in total Medicare benefits achieved by the physician group for its patient population and paid out in part based on the quality results.

CMS is also designing a pay-for-performance demonstration project to improve the quality and efficiency of care for chronically ill Medicare beneficiaries treated in small- and medium-sized physician practices, by providing assistance in adopting and using effective health information technology. The Medicare Care Management Performance Demonstration project will provide quality reporting and performance payments to physicians who meet or exceed performance standards in clinical delivery systems and patient outcomes, and will reflect the special circumstances of smaller practices. This demonstration is under development and will be implemented in Arkansas, California, Massachusetts, and Utah. Participating practices will receive technical assistance from the Quality Improvement Organizations in their areas, as well as bonus payments for achieving the project's objectives.

Resource Use. Measures of physician resource use have been used and are being developed by a number of public and private entities. In its March 2005 Report to Congress, MedPAC recommended that the "Secretary should use Medicare claims data to measure fee-for-service physicians' resource use and share results with physicians confidentially to educate them about how they compare with aggregated peer performance." CMS is preparing to implement the MedPAC recommendation in the near future on a pilot basis, using information derived from claims data. We are using existing claims data to simulate and test the measurement and quantification of individual physician patterns of practice, incorporating both services they order (including facility services) as well as services they furnish. As a next step, soon we expect to begin sharing the results with physicians confidentially to educate them about how they compare to peers.

CMS Demonstrations. As I have noted above and also as we have described in more detail in Enclosure 3, we are conducting a number of demonstrations and piloting various payment reforms to reward providers for better quality, better patient satisfaction, and lower overall health care costs in the Medicare fee-for-service program. Building on these initiatives, we recognize that many of the best opportunities for quality improvement cut across settings of care. We have projects in operation or in the advanced planning stages in the fee-for-service sector that will use standard quality measures to support better care coordination and continuity for beneficiaries with chronic illnesses across different care settings. In the Medicare Advantage program, we are moving toward full risk adjustment, which provides more resources to health plans that are able to attract and retain high-cost beneficiaries, thus providing stronger incentives to improve continuity and quality of care, while avoiding unnecessary services. In conjunction with these changes, we are seeing more efforts by Medicare Advantage plans to provide greater continuity of care and support for beneficiaries with predictably high costs, as well as more use of performance-based payments.

We want to build on all of these steps to give providers the support and resources they need to deliver better care and avoid unnecessary costs. Linking a portion of Medicare payments to valid measures of quality, using the kinds of approaches summarized here, would support better health care. These direct incentives would foster the development and implementation of innovative ideas and approaches that will result in improvements in the health care that our beneficiaries receive.

As evidenced by the early work of some of our demonstration projects, and the leadership Congress provided in the MMA creating incentives for hospital reporting, we are seeing meaningful results. These results are a promising foundation to support the most effective clinical and financial approaches to achieve better health outcomes for Medicare beneficiaries. We look forward to continuing to work closely with you and all of our stakeholders to advance these important initiatives to improve

quality and avoid unnecessary costs for Medicare beneficiaries and throughout our health care system. I also will provide this response to the cosigner of your letter.

Sincerely,

Mark B. McClellan, M.D., Ph.D.

Enclosure 1

DEVELOPING AND SELECTING STANDARDIZED QUALITY MEASURES

CMS has worked collaboratively with health care providers in an effort to develop measures of quality in various settings and to reduce the burden of their collection.

Development of Hospital Quality Measures

CMS and the Hospital Quality Alliance (HQA), which has representation from consumers, hospitals, practitioners, purchasers, and accreditation organizations, collectively selected a starter set of consensus-derived performance measures for public reporting. The measures were endorsed by the National Quality Forum (NQF) through a consensus development process that includes input from consumers, purchasers, clinicians, providers, researchers and quality improvement experts. The NQF is a non-profit organization that represents a broad range of health care stakeholders and provides endorsement of consensus-based national performance standards for measurement and public reporting.

This starter set of measures was incorporated into section 501(b) of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (the MMA), which provided a financial incentive for those hospitals that reported these measures. These measures are available at the following link on the CMS website: <http://www.cms.hhs.gov/quality/hospital/StarterSet.pdf>. On April 1, 2005, we launched the Hospital Compare website, which allows comparison of data on these measures from over 4,200 hospitals.

CMS and the HQA have identified an expanded set of measures that hospitals may choose to report without payment ramifications. An additional seven measures were released on April 1, 2005. These measures are available at the following link on the CMS website: <http://www.cms.hhs.gov/quality/hospital/HospitalQualityMeasures.pdf>. An additional five measures have been endorsed by the NQF and are due to be released later this year.

Development of Nursing Homes Measures

CMS currently uses data submitted via the Minimum Data Set (MDS) by facilities to produce 15 measures, endorsed by the NQF, for public reporting on Nursing Home Compare. These measures are available at the following link on the CMS website:

<http://www.cms.hhs.gov/quality/nhqi/Snapshot.pdf>.

CMS has been working closely with consumer groups and nursing home leaders through the Nursing Home Quality Initiative, a collaborative effort to improve quality of care in nursing homes. A key element of this effort is the development and improvement of specific quality measures. In addition to the 15 measures reported via the MDS, we are considering expanding this starter set to include measures that assess safety, patient functional status, patient experience, and personnel management. Safety measures would assess adverse events, such as inappropriate medication use or falls and other injuries. In addition, recent research has identified additional measures to assess functional status in short-stay Medicare patients, although many of the measures also reflect care provided to long-term patients as well. We are also interested in measuring the experience of care from the perspective of both patients and their families. Other possible measures might include assessing such items as: nursing home staff turnover rates; nursing director tenure; and staff immunization rates. Further, in its March 2005 report, MedPAC recommended the collection of data on a few admissions and discharge measures in order to provide insight into whether treatment goals (particularly for functional status) were met.

Development of Home Health Measures

Similar to the nursing home quality activities, CMS has also been working with leaders and advocates for the home health industry through our Home Health Quality Initiative. Under this initiative, measures are reported to CMS that provide information on how well the home health agencies provide care. Examples include: the status of a patient's physical and mental health; maintenance or improvement in the patient's ability to perform basic daily activities; and patient medical emergencies. These measures are based on information collected on Medicare or Medicaid patients who receive care at a Medicare certified home health agency.

In its March 2005 report, MedPAC recommended using the outcomes-based quality indicators (OBQIs) with appropriate risk adjustment as pay-for-performance metrics. The measures recommended by MedPAC include an assessment in improvement in the lives of home health patients and markers for adverse events that prompt home health agencies and surveyors to investigate further. OBQI measures are now in common use and have been studied for some time. A number of such measures have been endorsed by the NQF and are evidence based, well accepted, and not unduly burdensome. MedPAC has also recommended that an initial set of measures focus on improving patient's health and functioning as well as measures of stabilization, recognizing that often the goal of the home health agency is to simply stabilize the patient's condition.

Development of Dialysis Facility Measures

Initiated in 1998, CMS's Clinical Performance Measures (CPM) Project currently monitors 16 quality measures that are based on the National Kidney Foundation's Kidney Disease Outcomes Quality Initiative (K-DOQI) Clinical Practice Guidelines. These measures report the quality of dialysis services provided under Medicare in the areas of adequacy of hemodialysis and peritoneal dialysis, anemia management, and vascular access management. In addition to the CPMs, CMS also collects data on patient nutrition and is developing additional measures related to kidney transplant referral and ESRD bone metabolism.

CPM data are collected on a national random sample of adult in-center hemodialysis patients, all in-center hemodialysis patients less than 18 years of age, and a national random sample of adult peritoneal dialysis patients. Thirteen of the CPMs are calculated, and an annual report of these findings is published and made available to the public at the following link: www.cms.hhs.gov/esrd/1.asp. CPM data are not collected in numbers sufficient for calculating dialysis facility-specific rates. However, CMS is currently collaborating with the dialysis organizations to collect and transmit CPM data electronically on all their dialysis patients. We are also interested in measuring care from the patients' perspective.

Development of Physician Measures

Ambulatory care measures have also been developed by the American Medical Association's Physician Consortium for Performance Improvement, the National Committee for Quality Assurance (NCQA) and CMS. A set of about 99 ambulatory care measures was submitted to NQF for endorsement. These measures are available at the following link on the CMS website: <http://www.cms.hhs.gov/quality/AmbulatoryMeasures.pdf>. Although the endorsement process is still underway, to date 49 draft ambulatory measures have been endorsed. We expect that the final set will be released in July 2005. In addition, nine final diabetes measures, also known as the Diabetes Alliance measures have been endorsed by NQF.

A starter set of the ambulatory care measures, which is a subset of the measures submitted to NQF, has been developed by the Ambulatory care Quality Alliance (AQA), which is comprised of the Agency for Healthcare Research and Quality (AHRQ), America's Health Insurance Plans (AHIP), American College of Physicians (ACP) and American Family Physicians (AFP). We have been working closely with the AQA to develop this starter set of consensus-derived ambulatory quality measures for physician offices. We are also collaborating with many specialty societies to develop quality measures that reflect important aspects of the care of specialists and sub-specialists. For example, we are working closely with oncologists to develop measures of the adequacy of treatment planning and follow-up that oncologists furnish as part of their evaluation and management services; with cardiologists on measures of cardiac care for heart attack or heart failure conditions; and with cardiovascular surgeons on measures related to cardiac surgery.

Enclosure 2

SPECIALTY SOCIETIES—with Applicable Measures Developed or under Development

Internal Medicine	Applicable measures have been submitted to the National Quality Forum (NQF). The measures are currently in the public comment phase of the NQF process (e.g., Heart Disease: Coronary Artery Disease—percentage of patients who were prescribed a lipid-lowering therapy (based on current ATP III guidelines)).
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SPECIALTY SOCIETIES—with Applicable Measures Developed or under Development—Continued

	The Ambulatory care Quality Alliance (AQA) starter set of measures are applicable and ready (e.g., Hypertension: percentage of patient visits during which either systolic blood pressure >140 mm Hg or diastolic blood pressure >90 mmHg with documented plan of care for hypertension).
Internal Medicine— Cardiology	<p>The Coronary Artery Disease (CAD) and Heart Failure (HF) measures are applicable and ready (e.g., Heart Failure (HF): percentage of patients who also have LSVD who were prescribed ACE Inhibitor or ARB therapy; percentage of patients who also have LSVD who were prescribed beta-blocker therapy).</p> <p>The specialty society is also developing additional measures.</p>
Radiology	The American College of Radiology has appropriateness criteria for various diagnosis procedures (e.g., chest x-ray, computed tomography (CT) for detection of pulmonary embolism in adults). Measures on appropriateness of tests and appropriate communication of results are under development.
Surgery—Ophthalmology	<p>The specialty society has readily available practice guidelines and summary benchmarks, which outline the process of care elements that are important for quality of eye care (e.g., appropriate management of primary angle open glaucoma; appropriate post-op care for filtering surgery patients; complete post-op examination post cataract surgery).</p> <p>Further, the Academy helped initiate a NCQA performance measure for glaucoma screening consistent with Medicare's new benefit, which was incorporated into HEDIS 2006, and also has contributed to the development of the diabetes eye exam HEDIS measure, which is also part of the AQA's starter set of ambulatory care measures.</p>
Family Practice	<p>Applicable measures have been submitted to the NQF. The measures are currently in the public comment phase of the NQF process (e.g., percentage of patients who received an influenza immunization; percentage of patients who received a pneumococcal immunization; percentage of patients with diabetes with one or more A 1 C test(s) conducted during the measurement year).</p> <p>The AQA starter set of measures are applicable and ready (e.g., Hypertension: percentage of patient visits during which either systolic blood pressure > 140 mm Hg or diastolic blood pressure > 90 mm Hg, with documented plan of care).</p>
Surgery—Orthopedic	<p>Some Surgical Infection Prevention (SIP) and Surgical Care Improvement Project (SCIP) measures are directed for this specialty (e.g., prophylactic antibiotic received within 1 hour prior to surgical incision; surgical patients with recommended thromboembolism prophylaxis).</p> <p>Additional measures include the appropriate diagnosis and treatment of back pain.</p> <p>The specialty society is identifying and developing quality measures, e.g., the society has recently submitted 10 measures to NQF.</p>
Surgery—General	<p>The A V Fistula measure (Fistula First) could be refined for this specialty (e.g., the percentage of patients who have an autogenous arteriovenous fistula for dialysis vascular access).</p> <p>Most SIP/SCIP measures are directed for this specialty (e.g., prophylactic antibiotic received within 1 hour prior to surgical incision; surgical patients with recommended thromboembolism prophylaxis).</p>

SPECIALTY SOCIETIES—with Applicable Measures Developed or under Development—Continued

Internal Medicine— Hema-Oncology	<p>Patient experience of care measures are applicable, ready, and are currently being used in the cancer demonstration program (e.g., percentage of patients reporting pain; percentage of patients reporting nausea/vomiting; percentage of patients reporting fatigue).</p> <p>The specialty society is in the initial stages of developing measures that are related to their practice guidelines.</p>
Emergency Medicine	<p>The majority of the current hospital measures are applicable to emergency room physicians (e.g., aspirin and beta blocker treatment at arrival for acute myocardial infarction).</p>
Internal Medicine— Gastroenterology	<p>Applicable measures include appropriate attention to patient monitoring before, during and after the procedure when using conscious sedation measures; the percentage of patients who had appropriate screening for colorectal screening.</p>
Internal Medicine— Pulmonology	<p>Chronic Obstructive Pulmonary Disease (COPD) measures are applicable (e.g., percentage of patients with COPD who had a spirometry evaluation documented; percentage of patients with systemic corticosteroids for acute exacerbation).</p>
Anesthesiology	<p>Some SCIP measures are applicable (e.g., prophylactic antibiotic received within one hour prior to surgical incision; surgical patients with recommended thromboembolism prophylaxis).</p> <p>Additional measures include the appropriate evaluation of the patient—pre, during, and post procedure.</p>
Internal Medicine— Neurology	<p>Applicable measures include the appropriate treatment of ischemic stroke; stroke rehabilitation; diagnosis of dementia.</p>
Psychiatry	<p>Applicable depressive measures have been submitted to the NQF. The measures are currently in the public comment phase of the NQF process (e.g., Effective Acute Phase Treatment: percentage of patients who were diagnosed with a new episode of depression and treated with antidepressant medication and remained on an antidepressant for at least 180 days).</p>
General Practice	<p>Applicable measures have been submitted to the NOF. The measures are currently in the public comment phase of the NOF process (e.g., percentage of patients who received an influenza immunization; percentage of patients who received a pneumococcal immunization; percentage of patients with diabetes with one or more A 1 C test(s) conducted during the measurement year).</p> <p>The AQA starter set of measures are applicable and ready (e.g., Hypertension: percentage of patient visits during which either systolic blood pressure >140 mm Hg or diastolic blood pressure > 90 mm Hg, with documented plan of care).</p>
Pathology	<p>Practice guidelines are available but appear to be limited to interpretation. Measures on appropriateness of tests and appropriate communication of results are under development.</p>
Medicine—Nephrology	<p>ESRD and DOOI measures currently measure at the facility level but could be readily refined to measure at the physician level (e.g., Regular Measurement of the Delivered Dose of Hemodialysis: the delivered dose of hemodialysis should be measured at least once a month in all adult and pediatric hemodialysis patients).</p>
Physical Medicine and Rehabilitation	<p>Applicable measures include stroke rehabilitation and the prevention of complications.</p>

SPECIALTY SOCIETIES—with Applicable Measures Developed or under Development—Continued

Internal Medicine— Rheumatology	Applicable measures have been submitted to the NOF. The measures are currently in the public comment phase of the NOF process (e.g., Osteoarthritis: Functional Assessment—percentage of patients diagnosed with symptomatic osteoarthritis that were assessed for function and pain annually).
Surgery—Neurological	Some of the SIP/SCIP measures could be refined for this specialty (e.g., prophylactic antibiotic received within 1 hour prior to surgical incision; surgical patients with recommended thromboembolism prophylaxis).
Surgery—Colorectal	Some SIP/SCIP measures are applicable (e.g., prophylactic antibiotic received within 1 hour prior to surgical incision; surgical patients with recommended thromboembolism prophylaxis).
Nuclear Medicine	Applicable measures regarding the appropriate use of cardiac radionuclide imaging; appropriate protocols; appropriate patient preparation.
Preventive Medicine	Applicable measures have been submitted to NQF (e.g., percentage of patients who received an influenza immunization; percentage of patients who received a pneumococcal immunization; rate of mammography screening; rate of cervical cancer screening).

Enclosure 3

DEMONSTRATIONS AND PILOT PROGRAMS

Premier Hospital Quality Incentive Demonstration. CMS has partnered with Premier Inc., a nationwide alliance of not-for-profit hospitals, to conduct a demonstration program that is designed to improve the quality of inpatient care for Medicare beneficiaries by providing financial incentives. Under the Premier Hospital Quality Incentive Demonstration, about 270 hospitals are voluntarily providing data on 34 quality measures related to five clinical conditions: heart attack, heart failure, pneumonia, coronary artery bypass graft, and hip and knee replacements. Using the quality measures, we will identify hospitals in the demonstration with the highest clinical quality performance for each of the five clinical areas. Hospitals scoring in the top 10 percent for a given set of quality measures will receive a 2 percent bonus payment in addition to the normal payment for the service provided for Medicare discharges in the corresponding diagnosis-related groups (DRGs). Hospitals in the next highest 10 percent will receive a 1 percent bonus payment. In the third year of the demonstration project, hospitals that do not achieve absolute improvements above the demonstration baseline will be subject to reductions in payments. Preliminary results show that the modest financial incentives under the demonstration are sufficient to drive quality improvement.

Physician Group Practice Demonstration. CMS recently announced a demonstration project to test pay-for-performance in Medicare's fee-for-service payment system for physicians. The Physician Group Practice Demonstration will assess the ability of large physician groups to improve care that could result in better patient outcomes and efficiencies. Ten large (200+ physicians), multi-specialty physician groups in various communities across the nation will participate in the demonstration, which began operations in April 2005. Participating physician groups will continue to be paid on a fee-for-service basis, but they will be able to earn performance-based payments for implementing care management strategies that anticipate patients' needs, prevent chronic disease complications, avoid hospitalizations, and improve the quality of care. The performance payment will be derived from savings in total Medicare benefits achieved by the physician group for its patient population and paid out in part based on the quality results, which we will assess.

Medicare Care Management Performance Demonstration. CMS also plans to test a pay-for-performance system to promote the adoption and use of health information technology to improve the quality and efficiency of care for chronically ill Medicare beneficiaries treated in small- and medium-sized physician practices. The Medicare Care Management Performance Demonstration will provide performance payments for physicians who meet or exceed performance standards in clinical delivery systems and patient outcomes, and will reflect the special circumstances of smaller

practices. This demonstration is under development and will be implemented in Arkansas, California, Massachusetts, and Utah. Participating practices will receive technical assistance from the Quality Improvement Organizations in their areas, as well as bonus payments for achieving the project's objectives.

Medicare Health Care Quality Demonstration. CMS is also investigating how to enhance quality and safety in the Medicare Health Care Quality Demonstration. This demonstration program, which was mandated by the MMA, is a 5-year program designed to reduce the variation in utilization of health care services, and to increase quality and efficiency of care by encouraging area-level collaboration and coordination to improve the use of evidence-based care and overall area quality. We have sought public comment on the design of this demonstration and will consider these comments in a request for proposals. The project will be open to physician groups and other providers that are involved in integrated health care delivery, for example using effective interoperable electronic health information systems that improve quality and avoid unnecessary costs.

Chronic Care Improvement Program. This pilot program will test a population-based model of disease management. Under the program, participating organizations will be paid a monthly per beneficiary fee for managing a population of beneficiaries with advanced congestive heart failure and/or complex diabetes. These organizations must guarantee CMS a savings of at least 5 percent plus the cost of the monthly fees compared to a similar population of beneficiaries. Payment also is contingent upon performance on quality measures and beneficiaries and provider satisfaction. The program will generate data on performance measures that will be useful in improving the Medicare Program as a whole.

Disease Management Demonstration for Severely Chronically Ill Medicare Beneficiaries. This demonstration, which began enrollment in February 2004, is designed to test whether applying disease management and prescription drug coverage in a fee-for-service environment for beneficiaries with illnesses such as congestive heart failure, diabetes, or coronary artery disease can improve health outcomes and reduce costs. Participating disease management organizations receive a monthly payment for every beneficiary they enroll to provide disease management services and a comprehensive drug benefit, and must guarantee that there will be a net reduction in Medicare expenditures as a result of their services. To measure quality, the organizations must submit data on a number of relevant clinical measures.

Disease Management Demonstration for Chronically Ill Dual-Eligible Beneficiaries. Under this demonstration, disease management services are being provided to full-benefit dual eligible beneficiaries in Florida who suffer from advanced-stage congestive heart failure, diabetes, or coronary heart disease. The demonstration provides the opportunity to combine the resources of the state's Medicaid pharmacy benefit with a disease management activity funded by Medicare to coordinate the services of both programs and achieve improved quality with lower total program costs. The demonstration organization is being paid a fixed monthly amount per beneficiary and is at risk for 100 percent of its fees if performance targets are not met. Savings above the targeted amount will be shared equally between CMS and the demonstration organization. Submission of data on a variety of relevant clinical measures is required to permit evaluation of the demonstration's impact on quality.

End Stage Renal Disease (ESRD) Disease Management Demonstration. This demonstration is scheduled to begin later this year and extend for 4 years. Under this demonstration, organizations serving ESRD patients will receive a capitated payment to test the effectiveness of disease management models in increasing quality of care and containing costs. Eligible organizations will receive capitated payments and accept risk to provide a coordinated care benefit plan to ESRD enrollees. Incentive payments of up to 5 percent will also be made to plans for achieving quality improvements over the course of the demonstration. Quality measurement will be based on a quarterly submission of patient-level data on five key clinical indicators profiled in the CMS ESRD Clinical Performance Measures (CPM) Project. Initiated in 1998, the CPM Project currently monitors 16 quality measures that are based on the National Kidney Foundation's Kidney Disease Outcomes Quality Initiative (KDOQI) Clinical Practice Guidelines. These measures report the quality of dialysis services provided under Medicare in the areas of adequacy of hemodialysis and peritoneal dialysis, anemia management, and vascular access management. In addition to the CPMs, CMS will collect data on patient nutrition and develop additional measures related to kidney transplant referral and ESRD bone metabolism.

Care Management Demonstration for High Cost Beneficiaries. This demonstration, which is approaching implementation, will test models of care management in a Medicare fee-for-service population. The project will target beneficiaries who are

both high cost and high risk. The announcement for this demonstration was published in the Federal Register on October 6, 2004, and we accepted applications through January 2005. The payment methodology will be similar to that implemented in the Chronic Care Improvement Program, with participating organizations required to meet relevant clinical quality standards for the specific populations they target as well as guarantee savings to the Medicare program.

Dr. MCCLELLAN. My read of the current situation is, specialties account for about half of Medicare billing and have quality measures that are already established. These include specialties like internal medicine—you are going to hear from them soon—who have been providing tremendous leadership on many aspects of surgery and so forth, and about 40 percent or more have measures that are in development right now.

In addition, I have been talking with some Members of Congress who are physicians—there are getting to be more of them; I think that is probably a good thing—as well as outside experts about using proxies for quality measures where they are not developed yet. Just about all specialty societies have what are called evidence-based practice guidelines that they have developed, where the medical experts come together, review what all the evidence out there is and make some basic guideline recommendations for effective ways of treating patients. Whether or not those guidelines have been developed and are being used is another way that you can help focus on supporting physicians in using the best available medical evidence for their treatment.

So, through all of those kinds of approaches we have made a tremendous amount of progress, as Chairwoman Johnson said; and I do think that if there is continued momentum—which the Committee can help build—continued momentum from the medical specialty societies, which are really putting a lot of effort into this, I am very optimistic about having an even more comprehensive set of measures in the future.

Mr. HAYWORTH. Dr. McClellan, thank you very much. Madam Chairman, I appreciate the time.

Chairman JOHNSON OF CONNECTICUT. Mr. Lewis.

Mr. LEWIS. Thank you very much, Madam Chair. Thank you, Dr. McClellan, for being here today and for your testimony. Financial incentives are one way to influence behavior. What other mechanisms can be used to change practice patterns for maximized value? Are there other ways that payers can get involved beyond pay-for-performance initiatives?

Dr. MCCLELLAN. Absolutely. There are many ways, and the reason that there are many ways is because doctors care so much about providing the best possible care under the circumstances. Another area where we have been doing a lot of work lately with physician organizations and other medical experts involves helping to develop better evidence on what actually works. We have a tremendous amount of data in the Medicare Program on how patients are being treated that can help us understand and have been used in many studies, for example, on issues ranging from effectiveness of care to sources of health disparities to understanding better why different kinds of outcomes occur and what can be done about it.

So, supporting development of better evidence is one important way.

Another important way involves helping with the adoption of systems that can improve care in our Quality Improvement Organizations (QIO). We are now supporting local efforts for quality improvement activities, such as helping small physician groups evaluate and adopt electronic health record systems or providing some support for local quality improvement efforts, sharing ideas about things that physicians could do better together, learning from their mistakes, and things like that. So, there are a tremendous range of other activities beyond the payment systems themselves that can improve quality of care, and ideally all of these would be working together this time.

Mr. LEWIS. Thank you very much, Doctor. Doctor, I would like to take an opportunity, since we have you here, to ask you about some of my concerns and some of the physician concerns about the implementation of Medicare part D. At our last Subcommittee hearing almost every representative from an acute care center was very concerned that our seniors are very confused about this new benefit. We heard about the independent envelopes going to the poor seniors. What has been done to ensure that seniors have that question answered? We have known about this confusion for a long time. What is CMS doing? It is clearly not enough, because people are still confused.

Dr. MCCLELLAN. Well, this is our very broadest priority not just in CMS but throughout the U.S. Department of Health and Human Services (HHS), throughout the Administration and in work with you and many other Members of Congress, is to help make sure each beneficiary gets the information they need to make an informed choice about the drug coverage that is coming. Under the Medicare law, there is help for everybody with his or her prescription drug costs, but different people get help in different ways, and so we want to provide some very personalized assistance. Earlier you mentioned the mailing. That wasn't a mailing to everybody. It was a mailing to people who are getting their drug coverage through Medicaid now. We sent out close to 6 million letters. There were fewer than 100 that may have had this problem with the printing.

What we know, as I am sure you know from your contacts with constituents, is that you don't depend on any one mechanism for helping people find out about important new programs that affect their lives. You try to do it through many different ways. So, another approach that we are taking is through our Medicare and You handbook, which Congressman Stark and many of you commented on, in its earlier draft form, and we are revising it now. Another approach that we are taking is to work with outside organizations at the local level to help inform seniors in every State. In Georgia, we have doubled the funding for the State health insurance—

Mr. LEWIS. Could you repeat what you said about in the State of Georgia?

Dr. MCCLELLAN. In the State of Georgia, for example, there is a State Health Assistance Program that works, I think, through the Department of Aging, that is providing local face-to-face coun-

seling to beneficiaries about the changes that are coming. It is going to be providing help in the fall with making a decision about the coverage. They hold local meetings to inform seniors. They are doing trainer sessions. It is an excellent program. I have spent some time talking with some of their leadership myself. We are collaborating with many other organizations. You mentioned people who are living in assisted living or getting help with long-term care. Well, we are working directly with the organizations and health professionals that provide that care to help get information out.

Mr. LEWIS. Do we have copies of that handbook?

Dr. MCCLELLAN. The "Medicare and You" handbook has been in draft form. It is being finalized now. You will get copies of the final version before it goes out to seniors in the fall. In the meantime, Medicare has worked with many outside organizations to develop brochures, pamphlets, and other types of information customized to each type of beneficiary. That information is available on our Web site, and we can work with you and your office to make sure it gets to each of the specific types of seniors in your district that you want to reach. We are doing a tremendous amount of this local outreach right now because one of the most effective ways to reach people is face to face, involving people who are helping seniors make decisions—have been helping them make decisions for a long time about important decisions with regard to their health care and their finances.

Mr. LEWIS. When do you expect to have the handbook available?

Dr. MCCLELLAN. It will be mailed out by early October, and we will have the final version before then. I don't have an exact date. The key dates for seniors to know are that by October they will be able to get specific information about the plan options that are available to them, and then they can sign up from November 15th through May 15th of 2006. There is going to be some time to look at all this. You are right though, the more that we can reach seniors now and let them know what is coming the less confusion there will be and the more people will be able to make confident decisions sooner and easily about this important benefit. It is especially important if many of the beneficiaries in your district qualify for the extra help that will pay for 95 percent plus of their drug cost. So, we really do need to reach them, and I would be delighted to work with you more closely on that.

Mr. LEWIS. Thank you very much, Dr. McClellan.

Chairman JOHNSON OF CONNECTICUT. Thank you. Mr. McCrery.

Mr. MCCRERY. Thank you, Madam Chair. Dr. McClellan, before I throw you a bit of a curve ball I want to say how much I appreciate someone of your education and training and abilities agreeing to work in the Federal Government. Our country is fortunate to have someone of your capabilities serving our country, so thank you.

Dr. MCCLELLAN. Well, thank you. It is a lot of fun, and I am getting a lot of help, so that makes it easier.

Mr. MCCRERY. I am sure you have fun every day. Now for the curve ball. I want to depart for just a moment from the subject of today's hearing because I read an article in the New York Times

this morning, and I want you to confirm that it is true or say that it is not true, and then maybe expound a little bit. The article said that CMS announced that it was going to make available to medical providers across the country the current informational technology software being used by the Veterans Administration (VA). Is that correct?

Dr. MCCLELLAN. Yes, Congressman. This is a software system called VistA that the VA developed for electronic records in their hospitals. It is open software. It is not something that they pay to use. It is not proprietary. It is already available for free. The challenge for some physicians has been that it has not been very easy for them to adopt this in their offices. So, what we are doing is making the installation process a little bit easier, but it is essentially a system that has already been developed by the VA and that many doctors inside and outside the VA are already using to help get the benefits of electronic healthcare.

Mr. MCCRERY. How do you see—how do you envision CMS's effort—apparent effort to encourage the use of this particular technology, this software, dovetailing with the market's efforts to develop different bells and whistles, different approaches that might be superior to that?

Dr. MCCLELLAN. Absolutely. In fact, as I mentioned earlier, one of our QIO programs is to help small physician offices with adopting and installing electronic health records. The cost of these systems in many cases is significant. It is \$10-, \$20-, maybe \$50,000 or so for the practice of a few doctors. A lot of the burden is just getting that system up and running and finding one that can really do what you need it to do. There are a lot of systems out there that do that, and a lot of the help that we provide involves those commercial systems. So, for many specialties, many physician offices, they are going to want a system with additional bells and whistles that have additional capabilities, and that is great. I think our only goal is to make sure that all physicians are moving in the direction of electronic health care as quickly and as effectively as they can.

I think there is a vibrant private market for health information technology systems. It is going to get even better as we keep working together to establish interoperable standards that the private sector wants to use so that these systems can work with each other effectively. We are all for supporting that effort. That is key to the whole quality improvement effort behind performance-based payments.

Mr. MCCRERY. Well, as you know, we are developing legislation in the House, and the Senate is doing the same on the other side of the Capitol, which—I believe both approaches will call for HHS to involve the private sector in developing standards for interoperability. I am just curious if you have thought about how encouraging the widespread use of this one technology or this one software application that has certain standards obviously in it will affect the development by HHS of standards for interoperability that we think is best for the country.

Dr. MCCLELLAN. It is a very good question. The VA has been working with HHS and the rest of this Administration with this goal of interoperability. The adoption of those standards will be led

by the private sector. That is where we are looking for guidance here. As the adoption of those standards are adopted, the VA and every other part of the Federal Government is going to have to make sure they are in compliance with them. The VA is, I think, committed to making sure their software gets updated to be fully compliant with additional standards as they are developed. Again, I think there will be a broad range of privately developed products that will provide not only the sort of basic services the VA system does but many additional services as well and may even work with or on top of the existing VA software.

Mr. MCCRERY. Okay, good. Thank you.

Chairman JOHNSON OF CONNECTICUT. Mr. Doggett.

Mr. DOGGETT. Thank you very much, Madam Chairman; and thank you for your testimony and service, Dr. McClellan. Is it correct, with reference to the handbook that Congressman Lewis was just asking about, that all or parts of it have already gone to the printer?

Dr. MCCLELLAN. I believe that parts of it have gone to the printer. I don't know if the whole thing has gone to the printer.

Mr. DOGGETT. Well, the concern I have is that, while I hardly agree with the attitude and the manner in which you present it today—as far as cooperation with everyone here, as you may know or may not know the level of cooperation up to this point on this very important handbook has been rather minimal. The initial draft was not provided to our staff.

It was provided, I think, to some interest groups, including consumer interest groups; and eventually I gather, after some additional revisions were made in the draft, our staff was permitted to look at it in a time-restricted manner in the HHS offices; limited to looking at the entire publication for less than 2 hours. Since that time, staff has received no indication, of any type, as to whether any of the recommendations that they made have been accepted.

For example, the concern of our staff was that this handbook—you are well aware of the concerns that have been expressed not just about the Medicare prescription drug program but in the U.S. Department of Education, the U.S. Department of Agriculture—of using public resources to propagandize on behalf of the Administration. There was a particular feeling that people were being nudged toward HMOs and out of traditional Medicare without—hearing what the benefits were but not hearing what the limitations are. What opportunity is there at this point for any meaningful further comment or interaction on the contents of that book if part of it has already gone to the printer?

Dr. MCCLELLAN. Well, just to go back, Congressman, the whole document of that preliminary draft was made widely available—

Mr. DOGGETT. Not to our staff—

Dr. MCCLELLAN. Well, we received detailed comments from your staff on that first draft, and there were suggested changes like separating our now private fee-for-service health plans and Medicare that in the first draft had been combined with original fee-for-service government plans. The suggestion was that those should be separate, because the fee-for-service programs, the private ones, are small. Most Medicare beneficiaries in the original plan should have a clear description of that. Absolutely right. I agree with that,

and that has been taken in revisions. On the point that you just raised about Medicare Advantage plans versus the original Medicare Programming, there is some tradeoff there. On the one hand, under the Medicare Advantage Program, you are generally going to get——

Mr. DOGGETT. Let me say, I understand there is a tradeoff. Our concern about your handbook was that it only told about the pluses and not the minuses. I guess the bottom line is, at this point, when you talk about cooperation on the handbook, is there any cooperation that will occur other than you will give us a copy of what has already been printed up before everyone else gets it?

Dr. MCCLELLAN. I just want to review the comment process here, which is that we sent this draft, preliminary draft, labeled as such, out to literally hundreds of groups, and got comments back from them, from many of your staff, which we have taken in the revision process. That is how this works. You get input from all quarters, and then you finalize the document. You have to finalize it according to a specific time schedule because you have to mail this thing to 42 million beneficiaries to get it out on time.

Mr. DOGGETT. Let me shift to physician payments, but say, in conclusion, the amount of comment time that our staff had was about an hour and a half sitting in an office without the ability to take any of the papers back; and I think the level of cooperation we are being offered at this point is that we will get mailed a copy of the final published version ahead——

Dr. MCCLELLAN. That is what I am going to see to. It may not make you feel any better, but our staff got to do that full extensive round at first, and then there is more limited time. Once you have responded to all those comments, there is more limited time on the second round. I didn't get to see that second round for much longer than you did——

Mr. DOGGETT. Well, that troubles me——

Dr. MCCLELLAN. We do need to meet the timeframe——

Mr. DOGGETT. Let me ask you on physician's payment, before my time runs out. I believe you have indicated that we have got a projection of another 4.3 percent cut this next year.

Dr. MCCLELLAN. Yes, sir.

Mr. DOGGETT. How do you recommend that the Congress deal with that if you have not arrived at a long-term solution by that time?

Dr. MCCLELLAN. The kinds of ideas that we are discussing today, that would consider changing the way that we pay, instead of just paying based on volume of services, changing to a system that at least partly bases payments on quality on steps that help patients stay healthier, avoid unnecessary costs, keep overall costs down, is the right direction, and that is why we and so many medical groups, I think Members on both sides of the aisle, are interested in a better solution.

As Chairwoman Johnson said, we cannot abide 7 years of projected negative updates. As Congressman Stark said, and as the Administration has said, we cannot just add in more and more money to a system that is already having rapid increases in costs and in premiums. This is, I think, the best way forward. There has been a tremendous amount of progress in the last few months, and

I am confident that if we all keep working closely together and constructively, we can get to a better result than where we are currently headed.

Mr. DOGETT. Madam Chairwoman, if I may just follow up. Do you expect that the Administration will have a specific recommendation to our Chairwoman and to all of us about what we should do on the 4.3 percent cut that is coming up to physicians within a few months?

Dr. MCCLELLAN. I certainly hope that we can all come together on an effective approach. I know that you all are drafting legislation as well. We are happy to continue to provide technical support and help through that process.

Mr. DOGETT. Thank you.

Chairman JOHNSON OF CONNECTICUT. Mr. Hulshof.

Mr. HULSHOF. Thank you, Madam Chair. Welcome, Dr. McClellan. Picking up on Mr. McCrery's analogy, I am not sure if this is going to be a curve ball or a fast ball or right down the middle.

Dr. MCCLELLAN. As long as it is not aimed at the batter.

Mr. HULSHOF. For the Medicare population, cancer, diabetes, heart disease and stroke are the primary killers.

Dr. MCCLELLAN. Yes.

Mr. HULSHOF. Obviously these diseases also account for greatest the portion of spending in the Medicare Program. That is why over the past decade, and certainly during at least my short tenure here, Medicare has increased its focus on prevention, on screenings, chronic care, obviously in an effort to improve the overall health of those patients, those beneficiaries. In fact, in the Medicare Modernization Act, we did include these additional measures for early detection of disease in seniors. As a result of that, more and more health care is being delivered in the outpatient settings by physicians, versus, say, inpatients, or in the hospitals.

I certainly support that focus. I believe, as most of us do, that prevention, early detection and early diagnosis are essential, and here is where the pitcher is beginning to wind up, Dr. McClellan. I guess my question is whether the shift to more outpatient physician services is being calculated accurately in the current formula? It seems that, whether on your end or perhaps on our end, we are, through Medicare, encouraging beneficiaries to utilize more physician services, while at the same time, we are trying to control the volume of physician services through the SGR formula. So, let me just give maybe an open-ended question to you. Can you comment on how CMS projects utilization of physician services, and—maybe the tougher one, maybe a loaded question—are you confident that these calculations are accurate?

Dr. MCCLELLAN. Well, we certainly are trying to do the best job that we can. It is a very important topic. I think the especially good news is that recently, we have had a lot of constructive input from the AMA, from other medical professional groups, to help us understand, as Chairwoman Johnson mentioned at the outset, why exactly costs are going up. There is some discussion of this in my written testimony, so I would refer you to that. I think you are right that there are certainly some new treatments, new initiatives by doctors in their offices to help patients with those very costly chronic diseases, stay healthy and avoid complications.

The challenge that we have is that we have been peeling back the layers of what we are spending money on and that we are still seeing some cases where we are paying a lot of money, but it is not clear what we are getting for it. My worry is that we are not the experts here. What we would like to do is support doctors in doing the best job possible in preventing complications, and our current payment system does not do a great job of that. That is not something that is going to be fixed with more detailed calculations of exactly what caused spending growth.

Just to give you a couple of examples, you mentioned heart failure. Well, in the area of heart failure, we are seeing more patients paying for more specialists in any given time period. That may be good, but on the other hand, if you look at the way our payment system works, if one specialist spends time talking to a patient's internist, you may not need so much effort from another specialist, or by the time they get to the next specialist there won't be as much to talk about if all of these different doctors are communicating well, sharing records, managing the patient effectively together.

We pay less when they do that. We will pay more if they have more specialist visits, we do not give any bonus, in fact, it is kind of a penalty, because it means less use of lab tests and everything else if all of these doctors are actually talking to each other effectively about the patient's care. So, those are the kinds of problems that we are not going to get at just by making more accurate calculations about what exactly is causing the increases in spending. I do think we need to keep looking at those causes of increases in spending to find ways to better promote effective care by doctors. Again, I think more fundamentally, as many people here have said, we need a payment system that more directly gives doctors the support they need.

Mr. HULSHOF. I appreciate that answer.

Chairman JOHNSON OF CONNECTICUT. Thank you very much. Mr. Thompson.

Mr. THOMPSON. Thank you, Madam Chair. Thank you for being here, Doctor. What is the status of the demonstration projects that CMS is doing?

Dr. MCCLELLAN. Which one? We are doing a number of demonstrations.

Mr. THOMPSON. Aren't there three of them?

Dr. MCCLELLAN. For physician payments?

Mr. THOMPSON. Yes.

Dr. MCCLELLAN. Some of them are underway. Others are going to be starting soon. The ones that we are implementing are, in many cases, modeled on programs that are already being used by other health care payers in the private sector. So, we are spanning the spectrum between large multidisciplinary group practices, down to small individuals, one or two doctor offices, through the demonstration program.

Mr. THOMPSON. When are they expected to be completed?

Dr. MCCLELLAN. They will run over the next several years, and we expect to keep getting useful information within a year of the program starting. We had a hospital payment demonstration pro-

gram start a bit over a year ago, and we have already learned a lot from it in just 1 year.

Mr. THOMPSON. So, you do not think we should complete these before we implement the pay for performance?

Dr. MCCLELLAN. It depends on what you mean by implementing pay for performance. You will hear more from the medical specialties in a minute, but what some of them have proposed, and what I understand Chairwoman Johnson and others have been working on, would be to start out with paying for reporting information, not making the payments based on the information, but pay on reporting information. Then, over several years, move toward a performance-based payment. That would certainly be enough time to incorporate what we have learned from these demonstration projects.

Mr. THOMPSON. As we learn more from the demonstration programs, we can tune-up?

Dr. MCCLELLAN. That is right. I think the questions we need to answer are, how quickly and how extensively you can get down that road. I do think that there are good measures either available now or available by next year that we can start using as we march through that process.

Mr. THOMPSON. Thank you. In your testimony you had mentioned Lumetra and the work that they have been doing.

Dr. MCCLELLAN. Yes. That is the California QIO.

Mr. THOMPSON. I am assuming that the areas where they were working are, if not in my district, in districts or in areas similar to it.

Dr. MCCLELLAN. I hope so. I hope you will let me know if they are not.

Mr. THOMPSON. Can you give me an idea of what sort of problems they have been able to point out in regard to rural practices and the hurdles that they are facing?

Dr. MCCLELLAN. There are several problems for rural practices. One is they tend to be smaller, and so they are unlike a large multi specialty group, where it is easier for people to pool together, to invest in electronic record systems or other steps that help them work together better to improve quality. They may also be on their own more for making decisions about patients. So, when you are in an urban setting you are either practicing with doctors in different specialties or they are right close by for referrals, whereas in the rural setting you have to do more things on your own. That requires a different approach when you are thinking about quality improvement opportunities. What Lumetra has done is, just to take electronic records systems as an example, is try to identify systems that have already been working in certain rural doctor practices. It is unusual for rural docs to have electronic records, but it is not unheard of; it is increasing around the country now.

So, they have tried to develop tailored support programs to help rural doctors. They are on their own, they do not have a lot of staff, they do not have a lot of time to devote to figuring out how all of this software should be installed, so they have tried to help them follow some simpler rules or proven approaches to get those electronic record systems in place. Just as a side note on rural doctors, and these performance-based payments, when you look at some of

the performance measures that we are most interested in, and also look at overall cost of health care, which we want to keep down, many of these rural practices do very well already.

I do not know if it is just knowing your patients better than you can in an urban setting or what, but in terms of quality and cost, many of these rural doctors are doing well. I think they could do well under these performance-based payment systems, but just to make sure that happens we need to keep building on support programs like what Lumetra is doing.

Mr. THOMPSON. I yield back.

Chairman JOHNSON OF CONNECTICUT. Thank you. Mr. Emanuel.

Mr. EMANUEL. I would like to thank you, Dr. McClellan. You know I am about to say something that I really wish I was not going to say.

Dr. MCCLELLAN. You do not have to say it.

Mr. EMANUEL. When you hear it, I think you will hear why. Secretary Levitt is in my district, and I got an hour notice. He is in the district today. My gut tells me that if he was in Missouri, in my colleague's district, then he would be notified well in advance and invited. That would be true about my colleague from Arizona, that would be true about my colleague from Louisiana, that would be true about my colleague from Connecticut. We may have different views about the prescription drug benefit. I am not an expert like you, and I am not an expert like Dr. Levitt, but I have a couple of views about it. I would rather be talking about the pay for fee services today that we are supposed to be talking about.

Now, the prescription drug benefit is not very popular. There is a lot of questions about it out there. In fact, because of its complexity, there is a lot of hesitancy about it. Now, you are going to the Copernicus Center in my district today. I got about an hour notice that you were coming. I think I know something about what the people on the north side of Chicago think about that benefit, and I think I could be helpful. Now we have differences on re-importation, we have differences on direct negotiation, but I think this is a rank amateur move. Now, your agency was cited by the GAO for the advertisements you have done, and cited on the propaganda issue. A lot of people have some doubts about it because you politicized this process.

I hope the mailing you send out to the 42 million senior citizens does not include that same kind of political overture statement, because we can help get this benefit accepted. If you look at the acceptance by people for your discount card, which is unbelievably low, it comes from politicizing this process. I would prefer to use my time appropriately here, and I kind of resent that I am doing this, but I would like to, since you are the only one here from HHS, I would like to logger with you. We have our differences, but we serve the same people. I also have the eldest district in the State of Illinois. There are some senior citizens, for a former Congressman that happened to represent this district who were once hood ornaments to that Congressman's car because of their views of health care.

Now, I can help explain the benefit, whether I agree or disagree or vote for it. Now, having said that, we will talk at some other

point about reimportation, direct negotiation, how to deal with pricing. If this bill and the legislation was a little simpler, you would not require all of the explanation that is going to be involved in it. Now, with that, I would like to ask you, how do you ensure that been beneficiary will not pay more in this program than you would like to look at in the fee-for-service and the bonus structure?

Dr. MCCLELLAN. For the physician payment?

Mr. EMANUEL. Yes.

Dr. MCCLELLAN. I will answer that, but I do want to go back first to the issues raised earlier, because I truly appreciate your interest and willingness to get the facts out about the benefit itself. There a lot of people who disagree on what exactly should be in the Medicare drug benefit and how it should operate. I personally think these approaches that we are taking to get the prices down and to make sure that the benefits are up to date are going to make sure that Medicare's benefits don't fall behind like they have over the last 40 years, but there are differences about that. What we are doing with the outreach effort to educate seniors about the drug benefit is really about the facts of the benefit itself, and what it means for each of them. In your district, I did not realize this event was in your district this morning.

Mr. EMANUEL. It is going on right now.

Dr. MCCLELLAN. That is a locally-focused event, and it involves not just Republicans; Mayor Daly, I understand is going to be there, and many local organizations that are helping to get that information out to seniors to make sure that we are working together.

Mr. EMANUEL. I have a degenerative gene. I happen to do office hours at grocery stores. That is where I do my office hours. I greet people, whoever comes in and wants to talk or whatever. That is how I spend my time meeting my constituents. Now, I voted against this, but I have done a mailing explaining to people what the benefit is, where they can call. You and I and your office and your entire loyal public servants serve the same constituents. If I were somebody else on this panel, I would be rolling my eyes that I am wasting my time doing this with you personally. I really prefer not to be. The fact is, we have differences, but there are going to be people who are going to get that benefit. Now, we can have these differences, we are going to keep debating them out, and that is why politics is a good thing. There are some questions already about how this has been managed by HHS, and the politicization of this from the video that GAO cited you with. Now, I would suggest if you can stop continuing the politics, I did not need an hour-ahead call, you could have called ahead of time. I probably could not have made it because of votes here, but I would have appreciated it and could have helped you. Now, to the real issue at hand here that is also an important issue.

Dr. MCCLELLAN. I do want to follow up with you on that and make sure that we are working effectively together. I appreciate your commitment to getting the facts out. On physician payment, if you do not mind me running over for a minute or two on answering this important question, that is part of the challenge that we face. When we do anything that increases the total spending in part B, 25 percent of that increase is paid for by the beneficiaries.

So, that is why I think an approach of just adding more money into these same payment systems, which are rapidly increasing in cost, but are not helping to deliver high quality care as much as they could, is not the right way to go. The kinds of stuff that we are talking about, which would help doctors deliver better care, and avoid unnecessary services and help beneficiaries not only pay less money for their care, as a result, but also stay healthier are very important.

There are some challenges in getting these systems implemented, but there has been a tremendous amount of progress. I also promised to keep you and other Members of this Committee closely informed about any beneficiary impacts of these kinds of payment changes, because we do want to try to avoid that.

Chairman JOHNSON OF CONNECTICUT. Mr. Hulshof has a point to make, and I would like to give Mr. Cardin a chance.

Mr. HULSHOF. Just for the record, Madam Chairwoman, I would like the record to reflect that in the year 2000, the President of the United States, who my friend from Illinois used to work for, came to the University of Missouri, Columbia, presumably to talk about patients' bill of rights. I was not invited, even though the event was three blocks from my home. My political opponent for Congress was invited, as was our late Governor, Mel Carnahan, who was a Democratic Senatorial candidate. So, since the gentleman referenced me earlier, I wanted the record to reflect the political nature of that event as well.

Mr. EMANUEL. As you know from us being colleagues, I was gone in 1998. Had I been there, I surely would have invited you.

Chairman JOHNSON OF CONNECTICUT. Mr. Cardin.

Mr. CARDIN. Dr. McClellan, let me thank you for your testimony. I am a little bit concerned, though, about your last statement in that it gives me the impression that we are spending more money than we should for physician reimbursement, and we are not delivering the high level of care, at least that is just looking at the language that you just supplied Mr. Emanuel with. I am not so sure I agree with that statement. So, I, at least, want the record to reflect that I do think that the Medicare system does deliver a high level of care, and, yes, I think we need to improve it.

I think there is now no disagreement that the SGR needs to be eliminated as the payment structure for physicians. That seems to now be accepted, and we are now moving to where do we go from there, and I accept that. I just really want to put my concerns on pay for performance. I just do not quite understand what we are trying to achieve. Let me explain. It seems to me that if a physician provides high quality care, there is no need for a bonus, because that is what they should be doing.

Dr. MCCLELLAN. Right.

Mr. CARDIN. Second, if a physician provides the normal level of care, which is adequate care, there should not be a discount for that, they should get a reasonable reimbursement. So, I am not sure exactly what we are trying to achieve by these new standards. Maybe you can help me with that. I have the concern that if you set up a structure that gives extra payment for particular services, that the natural effect may well be to provide care for the reim-

bursement rather than providing care for the quality. Now, make me feel better about all of this.

Dr. MCCLELLAN. First of all, let me agree with you that Medicare does provide high quality care for millions of beneficiaries every day, and that is not just because of us paying the bills, it is because we have a very high caliber of health professionals in this country that we are able to work with in delivering this care. This is an area where I think a lot of people get it wrong in thinking about economics and physicians. Physicians are not there doing this job every day just because they want to make money, or even mainly because they want to make money. These are smart people. I know a lot of them. Not that I am one of them myself.

These are generally very smart people who are very committed to the work that they are doing, and they are there because they care about patients, because they want to deliver high quality care. In order to do that, they also have to keep their doors open. They have to be able to run their clinic, to pay their staff, to buy the equipment, and pay the bills that enable them to deliver high quality care. When we pay them in ways that gets in the way of that goal of high quality care, well, they cannot do their job as well as they could otherwise.

Just to give you one example, if a physician buys an electronic health records system, and then uses it to send e-mail reminders to their patients or to schedule visits more appropriately, or to enable them to contact the patient to head off complications or to get better information in on the patient's lab tests that are done elsewhere, what happens? They get paid less by Medicare. So, how can they make the investments in these kinds of quality-improving systems that they would like to be able to use to deliver better care if we do not have a payment system that supports that. Instead, what we will do is we will pay; if there are more lab tests done, if more of those patients come in to see that doctor or other doctors, if there are more complications for that patient with chronic illness, and so we end up spending more money getting less good health outcomes because we are not supporting doctors as effectively as we should. That is the goal.

Mr. CARDIN. I agree with everything you said. I just urge that this not be money driven. It seems to me that if you have a dollar amount you are trying to achieve, and that is going to compromise quality, because you have to reach that dollar amount, then you compromise the whole concept of what you are trying to do here. That is how I find too much policy driven here in Washington, not because of you, but because of our system here, and being so budget driven. So, I hope that in developing this, that you are going to reach out and meet with all of the different groups. I would really like to talk to you about the game plan that you have in reaching out to the different medical groups and groups that are out there to make sure that they have input before we do this.

I am concerned about this being driven more by money than driven by good health care policy. I could not agree with you more, our system can certainly be improved. We know that we have to get rid of the SGR. We all know that. That is going to cause those doors to close, and we do not want to see that happen.

Dr. MCCLELLAN. I think it is very important for this whole effort to involve a lot of leadership from the physician community. That is absolutely right.

Chairman JOHNSON OF CONNECTICUT. Thank you very much. We will hear that from the physician community. I can certainly provide you with the documents that they have circulated from which we drew the criteria and the measures in our draft proposal, which I would be glad to circulate too. Dr. McClellan, thank you very much. I know you need to leave at 2:30, so I won't proceed with some specific questions that I was holding until the end, but do I want to put them on the record.

Dr. MCCLELLAN. We will be happy to follow up with you on them.

Chairman JOHNSON OF CONNECTICUT. You know how strongly I feel about consistent decisions in Medicare, because I think they promote fair and equitable consequences. We have discussed this at great length on the issue of reclassification and recertification. I think the definition of physician services ought to be consistent. The fact that the definition of physician services is different under SGR than it is for the whole rest of Medicare is certainly distorting this program and hampering our ability to handle a fair and equitable reimbursement structure for physicians.

Second, I think the spirit of the law is every bit as important as the letter of the law. While the letter says that the SGR has to be accommodated with changes in law and regulation, I would certainly maintain that program memorandum and national coverage decisions do have office visit implications, and those ought to be better reflected, and that is something we are going to have to look at carefully if we cannot do something truly more intelligent, which is to repeal the whole system, and substitute for it a more intelligent payment system, but also one that analyzes growth and evaluates it for appropriateness.

There is no evaluation of appropriateness going on right now, although I know you and your staff are taking apart this big increase from the last year to begin to look at that. The new payment system, the new profiling effort will give us the tools we need to judge appropriateness of service increases, and we do not have those now. So, I do not want the system to be destroyed through a 15-percent increase that may very well represent a growth in preventive services, in quality practices. We just do not know. So, we have a lot of work to do together, if we are going to prevent the current law from going into effect. I hope you and your staff will work closely with us, and will be open to the level of change that we have to make if we are going to go forward in the future in the way you propose.

Dr. MCCLELLAN. Thank you very much.

Chairman JOHNSON OF CONNECTICUT. Thank you for being with us. If the next panel would please come forward. Good afternoon and welcome to the hearing. We hope that you will summarize your testimony in roughly 5 minutes. This is a very important subject, and you have written very interesting testimony. Then we will have time for some questions. Thanks.

**STATEMENT OF JOHN H. ARMSTRONG, M.D., MEMBER, BOARD
OF TRUSTEES, AMERICAN MEDICAL ASSOCIATION**

Dr. ARMSTRONG. Thank you, Chairman Johnson. My name is John Armstrong. I am a trustee of the AMA, and a practicing trauma, critical care and general surgeon from Miami, Florida. The AMA would like to commend you, Madam Chairman, and Members of the Subcommittee, for your leadership in recognizing the need to replace the current Medicare physician payment formula. We also appreciate your repeated efforts, Madam Chairman, with Chairman Thomas, in pressing CMS to make administrative changes to the physician payment formula. This would help Congress enact a new formula that keeps pace with physician practice costs by lowering the cost of legislation.

We also commend Representatives Shaw and Cardin, and the over 100 cosponsors of H.R. 2356, the Preserving Patient Access to Physicians Act of 2005. This bill would replace the current physician payment formula. Madam Chairman, today we are here to discuss the legislation you are developing. We understand it would repeal the fatally flawed physician payment formula, and implement a value-based purchasing program for Medicare physician services. The AMA and its member physicians are staunchly committed to quality improvement. Over the last 5 years, the AMA has dedicated over \$5 million in convening the physician consortium for performance improvement for the development of performance measures and related quality activities.

As a result of these efforts, CMS is now using these measures developed by the consortium in demonstration projects on pay-for-performance authorized by the Medicare Modernization Act. In June, our house of delegates adopted principles and guidelines for pay-for-performance programs, and these are attached to our written testimony. Overall, many of the elements we understand would be included in your legislation are consistent with a number of these principles and guidelines.

For example, we understand your goals in developing legislation are: To repeal the SGR and provide positive updates for physicians that reflect increases in practice costs; to allow voluntary physician participation; and to require evidence-based valid performance measures developed by the medical specialties in a transparent process. We want to work further with you and Members of the Subcommittee to address areas of concern.

Pilot testing prior to full implementation is essential. Measures of efficiency should not simply reward the lowest cost provider while ignoring quality of care. Efficiency measures must meet the same evidence-based standards as quality measures. There also needs to be a reliable method for risk adjustment. In addition, we are concerned about potential adverse effects of public reporting, such as exacerbating disparities in care for minority and other vulnerable populations. Providing patients with flawed information would undermine the goals of value-based purchasing, and violate the physician's oath of, first, do no harm.

Physicians should be fairly reimbursed for their administrative costs, especially for information technology systems necessary for the collection and transmission of accurate quality data. Finally, the AMA appreciates the Chairman's recognition that the current

flawed physician payment formula cannot coexist with a value-based purchasing program. Value-based purchasing may save dollars for the program as a whole by reducing hospitalizations, but the majority of measures, such as those focused on prevention and chronic disease management ask physicians to deliver more care. If the physician payment or SGR formula is retained the so-called reward for physicians will be additional pay cuts. This would only compound an ongoing serious problem. Physician pay cuts of 31 percent over the next 7 years are projected beginning January 1, 2006.

A recent AMA survey showed that these cuts will impair patient access. For example, more than a third of physicians would decrease the number of new Medicare patients they accept. More than half would defer the purchase of information technology that is necessary to make value-based purchasing work. A majority will be less likely to participate in Medicare Advantage. It is clear that the current physician payment formula must be replaced. We agree with your conclusion, Madam Chairman, and the conclusion of Chairman Thomas, that CMS should help lower the cost of enacting a new formula by using its authority to remove drugs from the SGR retroactively, and including in the payment formula increased spending due to national coverage decisions and government health promotion policies. We look forward to working with the Subcommittee on a new payment system that truly benefits our patients. Thank you.

[The prepared statement of Dr. Armstrong follows:]

**Statement of John H. Armstrong, M.D., Member, Board of Trustees,
American Medical Association**

Chairman Johnson, Ranking Member Stark and Members of the Subcommittee, the American Medical Association (AMA) appreciates the opportunity to provide our views today regarding value-based purchasing for physicians under the Medicare program.

The AMA would like to commend you, Madam Chairman, and each Member of the Subcommittee, for all of your hard work and leadership in recognizing the fundamental problems inherent in the Medicare physician payment update formula and the need to replace the flawed formula. A new formula that keeps pace with physician practice cost inflation is critical. Without it, we are in grave danger of a Medicare meltdown that would present serious access problems for our nation's senior and disabled patients.

We also greatly appreciate, Madam Chairman, that you are in the process of developing legislation that would repeal the current physician sustainable growth rate (SGR) formula and replace it with an alternative system that is intended to better reflect physician practice costs. The draft legislation would also implement a value-based purchasing program for Medicare physicians' services. Overall, many of the elements that we understand you are considering for inclusion in your legislation would be consistent with AMA principles recently adopted by our House of Delegates relating to value-based purchasing programs (or "pay-for-performance" programs), as we discuss further below, along with a couple of issues about which we urge further consideration.

In addition, the AMA extends its gratitude to Chairman Thomas and Subcommittee Chairman Johnson for your repeated efforts in pressing the Centers for Medicare and Medicaid Services (CMS) to join forces with Congress to replace the flawed physician payment formula. As your letter to CMS Administrator McClellan, dated July 12, 2005, states: "A permanent legislative fix to the Sustainable Growth Rate (SGR) formula would be prohibitively expensive given current interpretation of the formula, but could proceed through our joint efforts combining administrative and legislative action." The letter also affirms CMS' authority to remove the costs of drugs, back to the base period, from calculation of the SGR, and requests that CMS review its procedures for determining the costs of national coverage decisions (NCDs). **The AMA adamantly agrees with the Chairmen that CMS should**

retroactively remove drugs from the SGR and reflect in the SGR increases in physician spending due to NCDs, and we urge CMS to do so for the 2006 physician payment rule.

We also commend Representatives Shaw and Cardin and the over 90 co-sponsors of H.R. 2356 (the *Preserving Patient Access to Physicians Act of 2005*) for your leadership and efforts in addressing the flawed Medicare physician payment formula. Your bill also would relieve looming Medicare physician access problems by repealing the current SGR formula and implementing positive updates in 2006 and beyond that would reflect increases in the cost of practicing medicine.

VALUE-BASED PURCHASING FOR PHYSICIANS AND CURRENT SGR FORMULA CANNOT CO-EXIST

The AMA appreciates the Chairman's recognition that the current flawed Medicare sustainable growth rate (SGR) physician payment formula must be replaced and cannot co-exist with a value-based purchasing program for physicians. The end-goals of the SGR and value-based purchasing are in conflict.

Value-based purchasing programs are based on the notion that the management of potentially costly conditions in the physician's office will prevent or shorten hospitalizations paid for under Medicare Part A. This also means, however, that more care will be delivered in physician offices under Medicare Part B. Thus, although pay-for-performance may save money for Medicare Part A or to the program as a whole, it likely will result in increased spending on physician Part B services. During his May 11, 2004 testimony before this Subcommittee, CMS Administrator, Dr. Mark McClellan, suggested that one of the agency's quality improvement projects, the Chronic Care Improvement Project, "may actually increase the amount of (patient-physician) contact through appropriate office visits with physicians."

Increased Medicare spending on Part B physicians' services would trigger additional Medicare pay cuts for physicians because, as discussed further below, Medicare pays for Part B physician services based on the SGR spending target. If physician spending exceeds the SGR target, Medicare payments to physicians are cut. In other words, pay-for-performance and the SGR are inconsistent concepts. This would only compound ongoing serious problems resulting from application of the current SGR physician payment formula.

The flaws in the SGR formula led to a 5.4% payment cut in 2002, and additional cuts in 2003 through 2005 were averted only after Congress intervened. The Medicare Trustees project that physicians and other health professionals face steep pay cuts (about 26%) from 2006 through 2011. If these cuts begin, on January 1, 2006, average physician payment rates will be less in 2006 than they were in 2001, despite substantial practice cost inflation. These reductions are not cuts in the rate of increase, but are actual cuts in the amount paid for each service. Physicians simply cannot absorb these draconian payment cuts and, unless Congress acts, physicians may be forced to avoid, discontinue or limit the provision of services to Medicare patients.

The AMA conducted a survey of physicians in February and March 2005 concerning significant Medicare pay cuts from 2006 through 2013 (as forecast in the 2004 Medicare Trustees report.) Results from the survey indicate that if the projected cuts in Medicare physician payment rates begin in 2006:

- More than a third of physicians (38%) plan to decrease the number of new Medicare patients they accept;
- More than half of physicians (54%) plan to defer the purchase of information technology;
- A majority of physicians (53%) will be less likely to participate in a Medicare Advantage plan;
- About a quarter of physicians plan to close satellite offices (24%) and/or discontinue rural outreach services (29%) if payments are cut in 2006. If the pay cuts continue through 2013, close to half of physicians plan to close satellite offices (42%) and/or discontinue rural outreach (44%); and
- One-third of physicians (34%) plan to discontinue nursing home visits if payments are cut in 2006. By the time the cuts end, half (50%) of physicians will have discontinued nursing home visits.

A physician access crisis is looming for Medicare patients. While the MMA brought beneficiaries important new benefits, these critical improvements must be supported by an adequate payment structure for physicians' services. There are already some signs that access is deteriorating. A MedPAC survey found that 22% of patients already have some problems finding a primary care physician and 27% report delays getting an appointment. **Physicians are the foundation of our na-**

tion's health care system. Continual cuts (or even the threat of repeated cuts) put Medicare patient access to physicians' services at risk. They also threaten to destabilize the Medicare program and create a ripple effect across other programs. Indeed, Medicare cuts jeopardize access to medical care for millions of our active duty military family members and military retirees because their TRICARE insurance ties its payment rates to Medicare.

The AMA is happy to have the opportunity today to address problems with the physician payment formula, as well as administrative action that can be taken now to help alleviate the cost of enacting a new physician payment formula. We also look forward to working with the Subcommittee and CMS to ensure a stable, reliable payment system that preserves patient access and keeps up with the costs of practicing medicine. This would treat physicians similarly to other Medicare providers, such as hospitals, home health agencies and skilled nursing facilities.

VALUE-BASED PURCHASING PROGRAMS FOR PHYSICIANS

AMA Commitment to the Development of Effective Quality Improvement Programs

The AMA is committed to quality improvement, and we have undertaken a number of initiatives to achieve this goal. Over the last five years, the AMA has spent over \$5 million in convening the Physician Consortium for Performance Improvement for the development of performance measurements and related quality activities. The activities of the Consortium, as well as other AMA initiatives in performance improvement are described in the attached document.

AMA Pay-for-Performance Principles and Guidelines

As quality improvement efforts have evolved, so has the concept of value-based purchasing (or pay-for-performance). The AMA believes that physician pay-for-performance programs designed properly to improve effectiveness and safety of patient care may serve as a positive force in our healthcare system. If done improperly, however, they could harm patients, and, thus, in our ongoing efforts to advance the development and effective implementation of pay-for-performance programs, the AMA's House of Delegates adopted in June comprehensive pay-for-performance (PFP) principles and guidelines.

Overall, these principles address five broad aspects of pay-for-performance programs: (i) quality of care; (ii) the patient/physician relationship; (iii) voluntary participation; (iv) accurate data and fair reporting; and (v) fair and equitable program incentives. Associated with each principle, however, are more specific guidelines. These principles and guidelines are attached.

Similar to these AMA principles, which support the use of quality of care measures created by physicians across appropriate specialties, the code set used to capture quality of care measures also needs to be created by physicians working with the specialty societies. The CPT codes set, using the CPT editorial process, provides the appropriate combination of clinical methodological rigor and broad stakeholder expertise to support the application of codes to quality of care measures. In fact, the AMA/CPT Editorial Panel has already established a Performance Measurement Advisory Group (PMAG) utilizing nationally recognized performance measurement experts to provide guidance on the development of CPT Category II performance measurement codes. To date over 30 CPT Category II codes have been developed utilizing an inclusive and thorough process.

We strongly urge use of the CPT Editorial Panel process and use of the CPT Category II codes as the preferred code set for transmitting performance measurement information under pay for performance programs.

Physician Value-Based Purchasing Legislation

The value-based purchasing legislation being developed by Chairman Johnson appears to be consistent with a number of key AMA PFP guidelines discussed above. For example, we understand the legislation would require the development of a value-based purchasing program for physicians' services that contains at least the following elements: (i) allocation of new funds for physicians who report and meet performance measures; (ii) voluntary physician participation; (iii) evidence-based performance measures developed in a transparent, open process that allows each of the individual medical specialty societies to have input into the process of developing performance measures; (iv) allowance for variations in individual patient care based on a physician's clinical judgment; (v) performance measurement that is scored against both absolute values and relative improvements in those values; (vi)

a phase-in of the program during 2007, 2008 and 2009; (v) safeguards against patient de-selection; (vii) measures that take into account patient non-compliance; (ix) patient privacy; (viii) the option by physicians to bill at a group level; and (xi) the ability for physicians to review and comment on and appeal performance ratings, with a requirement that physicians' comments be released along with their rating.

There are several areas of concern that the AMA urges the Subcommittee to consider as it moves forward in developing value-based purchasing legislation. First, all physicians should receive a base payment update, while physicians achieving quality goals can receive a bonus payment. In addition, any pay-for-performance program needs to be pilot tested prior to full implementation. Since value-based purchasing is a completely new concept with regard to Medicare payment for physicians' services, pilot testing is critical for determining whether this type of payment system achieves its intended purpose. Pilot tests would also help identify program "glitches" and any needed modifications prior to full implementation of the program.

Measures of efficiency are another strong area of concern. Efficiency measures have the danger leading to rewards for the lowest-cost provider, while ignoring quality of care. Thus, it is imperative that efficiency measures meet the same standards as are applied to quality measures. These measures must be evidence-based, valid measures developed through a transparent process that allows input from the medical specialties. Efficiency cannot only relate to cost issues, as we have learned from the experience of UnitedHealthcare. Its United Performance insurance product was introduced this year, but two large medical groups have already informed United they will not participate in the performance program because performance ratings for efficiency essentially are based on United's financial liability, not the quality of care provided. Finally, there must be broad-based consensus regarding what constitutes appropriate levels of care before measuring for efficiency.

Development of risk-adjustment techniques are of great concern to the physician community. Currently, there is no reliable method for risk-adjustment, which has grave consequences for purposes of determining a fair comparison of physician performance, payment and public reporting, as discussed below.

The AMA also is very concerned about public reporting, which if not approached thoughtfully, can have unintentional adverse consequences for patients, including, for example, patient de-selection in the case of those with certain ethnic, racial, socioeconomic or cultural characteristics that make them less compliant. Further, health literacy may not be adequate to comprehend basic medical information. Yet, programs must be designed so that appropriate information must be available to patients to enable them to make educated decisions about their health care needs. If done correctly, public reporting has the potential to help provide such appropriate information to patients. There remain, however, several critical issues that must be resolved before public reporting provisions can be implemented. There needs to be a method for ensuring that any publicly reported information is: (i) attributable to those involved in the care; (ii) appropriately risk-adjusted; and (iii) accurate, as well as relevant and helpful to the consumer/patient. Moreover, in accordance with the AMA guidelines, physicians must have the opportunity for prior review and comment and the right to appeal with regard to any data that is part of the public review process. Physicians should also have the right to have their comments included with any publicly reported data.

Further, in implementing performance measures, it is important to learn from private sector programs already in existence. We know from some private sector programs that application of measures is more effective if they are implemented on a graduated basis. It is best to begin by implementing only a limited number of measures to assess how well they work, and then build upon the program from that starting point. Thus, we recommend that pay-for-performance legislation include limits on the number of measures with which physicians must comply over certain time periods.

The AMA also urges that any value-based purchasing program ensure that physicians are not burdened with additional administrative costs, especially for information technology systems that are needed to participate in the program. As discussed above, physicians cannot continue to absorb unfunded government mandates, and value-based payments for participation in the program should not be undermined by administrative costs.

Finally, the AMA wishes to raise overall factors to be considered as we move forward in developing value-based purchasing legislation for physicians: (i) physician practices are vastly different in size and type across the country, and, in stark contrast to hospitals, which are fairly homogenous, one size does not fit all; (ii) the number of patients needed to achieve a statistically valid sample size; (iii) the desire to keep the data collection burden low, while at the same time maintaining accuracy of the data; (iv) level of scientific evidence needed in establishing appropriate meas-

ures; (v) the ability to trace a performance measure back to one or many physicians involved in a patient's care; and (vi) the complexities of distributing payments when multiple physicians are involved in a patient's care, and without violating any fraud and abuse laws and regulations.

We commend Chairman Johnson for your sensitivity to these important factors, and we look forward to working with you to achieve a new payment system for physicians that keeps pace with the cost of practicing medicine and rewards physicians for the quality of care they provide.

SPENDING TRENDS

Medicare pays for services provided by physicians and numerous other health care professionals based a target rate of growth, called the sustainable growth rate (SGR). If Medicare spending on physicians' services exceed allowed spending in a particular year, physician payments are cut in the subsequent year. Conversely, if allowed spending is less than actual spending, physician payments increase.

Only physicians (and other health professionals whose payments are tied to the physician fee schedule) are subject to arbitrary cuts due to factors beyond their control. Every other category of health care provider receives positive updates, based on a measure of inflation in their practice costs. For example, CMS recently announced positive updates of 2.5% for home health services and 3.2% for hospitals.

On March 30, the Centers for Medicare and Medicaid Services reported that Medicare spending on physician services grew by 15% in 2004. Other Medicare data, including the 2005 Medicare Trustees Report, suggests spending growth of 12% to 13%. About 7% represents an increase in services per patient. This follows utilization increases of about 5.5% in 2001, 6% in 2002 and 5% in 2003. **What happened in 2004 is not some "unprecedented" spending spike.** It is the continuation of a trend brought about by expanded life-spans, more chronic disease and better treatments.

Nevertheless, it is not surprising that Medicare spending on physician services continues to increase. First, Medicare's two public trustees have noted that much of the growth in physician services can be traced to technological advances. Revolutionary changes in the practice of medicine have made it possible to keep millions of Medicare's elderly and disabled beneficiaries alive and active well into their 80s. Second, the prevalence of expensive chronic conditions such as kidney failure, heart disease and diabetes has increased dramatically, despite these vast improvements in mortality and quality of life. More than three-fourths of Medicare beneficiaries now have at least one chronic illness and about two-thirds have a least two and 20% have five or more. **Thus, with the positive results of medical advances and the increase in widespread chronic conditions among the elderly, Medicare spending on physician services is a good investment.** Congress has recognized the value of investing in physician services by twice intervening to avert sharp Medicare cuts.

CMS has also noted that an increase in Medicare payments for physician and other health professionals would, in turn, increase the Medicare Part B premium for beneficiaries. Physician pay cuts, however, will ultimately cost beneficiaries more because these cuts will force physicians to discontinue providing certain services in the physician's office. Rather, patients will have to receive these services in higher-cost hospital settings. This means that Medicare patients will experience more inconvenience, exposure to life-threatening infections, and higher deductibles and co-payments when they are treated in the hospital. In fact, increased spending on hospital outpatient services, whether due to the hospital payment update or utilization increases, also increases beneficiary premiums.

PROBLEMS UNDER THE SUSTAINABLE GROWTH RATE SYSTEM

There are two fundamental problems with the SGR formula:

1. Payment updates under the SGR formula are tied to the gross domestic product, which bears little relationship to patients' health care needs or physicians' practice costs; and
2. Physicians are penalized with pay cuts when Medicare spending on physicians' services exceeds the SGR spending target, yet, the SGR is not adjusted to take into account many factors beyond physicians' control, including government policies, that although good for patients, promote Medicare spending on physicians' services. (as further discussed below under "Administrative Action Needed.")

Problems with the Payment Formula Due to GDP

GDP Does Not Accurately Measure Health Care Needs

The SGR permits utilization of physicians' services per beneficiary to increase by only as much as GDP. The problem with this "relationship" is that GDP growth does not track the health care needs of Medicare beneficiaries. For example, when a slowed economy results in a decreased GDP, the medical needs of Medicare patients remain constant, or even increase, despite the economic downturn. Yet, physicians and numerous other health professionals, whose Medicare payments are tied to the physician fee schedule and who are doing their best to provide need services, are penalized with lower payments because of a slowly growing economy, resulting in the decreased GDP. Further, GDP does not take into account the aging of the Medicare population, technological innovations or changes in the practice of medicine.

Historically, health care costs have greatly exceeded GDP. Yet, the SGR is the only payment formula in Medicare tied to that index. In contrast, payments for hospitals, skilled nursing facilities and home health, for example, are all tied to their inflationary pressures.

Technological Innovations Are Not Reflected in the Formula

The Congressional Budget Office has said that Medicare volume increases are due to "increased enrollment, development and diffusion of new medical technology" and "legislative and administrative" program expansions. The SGR system's artificial cap on spending growth ignores such medical advances when it limits target utilization growth to GDP growth.

The United States' population is aging and new technologies are making it possible to perform more complicated procedures on patients who are older and more frail than in the past. Over the last decade, life expectancy has risen by a year for women and two years for men. Life-spans for both sexes rose by about a half year just between 1999 and 2002, and 65-year-olds of both sexes now can expect to become octogenarians. Improvements in the field of anesthesia and surgery make it possible to operate on older and older patients when complex surgery is required. People 80 and older now frequently undergo extensive surgery to prevent heart attacks and strokes.

Both Congress and the Administration have demonstrated their interest in fostering advances in medical technology and making these advances available to Medicare beneficiaries through FDA modernization, increases in the National Institutes of Health budget, and efforts to improve Medicare's coverage policy decision process.

The only way for technological innovations in medical care to really take root and improve care is for physicians to invest in those technologies and incorporate them into their regular clinical practice. The invention of a new medical device cannot, in and of itself, improve health care—physicians must take the time to learn about the equipment, practice using it, train their staff, integrate it into their diagnosis and treatment plans and invest significant capital in it. Although the Medicare hospital payment system allows an adjustment for technological innovations, the physician payment system does not do so. The physician payment system is the only fee structure of Medicare that is held to GDP, and no other Medicare payment system faces as stringent a growth standard.

Government efforts to foster technological innovations could be seriously undermined as physicians now face disincentives to invest in new medical technologies or to provide them to Medicare beneficiaries.

Site-of-Service Shifts Are Not Considered in the Formula

Another concern that is not taken into account in the SGR formula is the effect of the shift in care from hospital inpatient settings to outpatient sites for certain medical procedures. For example, when the 2005 Medicare Trustees report was released, CMS noted that expenditures for inpatient hospital services covered by Part A were lower than previous forecasts, but failed to mention that lower inpatient spending was a contributor to increased Part B spending for physicians' services.

It has been a goal by Congress and the Bush Administration to utilize more physician services through disease management and prevention initiatives in order to avoid expensive hospitalizations and nursing home admissions. Technological innovations have also made it possible to treat many services that once required hospitalization in physicians offices instead. Physicians are keeping seniors with chronic diseases out of hospitals by managing their care in the office. Hospital days per 1000 population between 1995 and 2002 declined by more than 15% among 65 to 74 year olds and by more than 10% for those 75 and older.

Where inpatient care is avoided, deductibles are reduced from about \$900 to about \$100; if ambulatory care is involved, co-payments are limited to 20% of Medicare's

allowed charge in physician offices compared to up to 45% in a hospital outpatient department.

While these trends have led to the treatment of increasingly complex cases in physicians' offices, the increased use and intensity that results is not recognized in the SGR formula.

Beneficiary Characteristics Are Not Reflected in the Formula

A related factor that also is unrecognized in the SGR formula is changes over time in the characteristics of patients enrolling in the fee-for-service program. For example, increases in patients diagnosed with, or having complications due to such diseases as obesity, diabetes and end stage renal disease, require greater utilization of physicians' services. Yet, these types of changes in beneficiary characteristics are not reflected in the SGR.

ADMINISTRATIVE ACTION NEEDED TO ASSIST CONGRESS IN REPLACING THE SGR

Apart from the inherent problems in the physician payment formula, there are other problems with implementation of the SGR that seriously threaten patient access and inequitably affect payment updates due to factors that are beyond physicians' control.

1. *CMS Must Remove Medicare-covered, physician-administered drugs and biologics from the physician payment formula, retroactive to 1996*

CMS has the Authority to Remove Drugs from the SGR

The AMA joins Chairman Thomas and Subcommittee Chairman Johnson in urging CMS to remove spending on physician-administered drugs from calculations of the SGR, retroactive to 1996. As discussed above, in the July 12, 2005, letter to Administrator McClellan, Chairmen Thomas and Johnson affirmed CMS' authority to remove spending on physician-administered drugs from calculation of the SGR.

When CMS calculates actual Medicare spending on "physicians' services," it includes the costs of Medicare-covered prescription drugs administered in physicians' offices. The July 12 letter explains that CMS has excluded drugs from "physicians' services" for purposes of administering other Medicare physician payment provisions. Thus, removing drugs from the definition of "physicians' services" for purposes of calculating the SGR is a consistent reading of the Medicare statute. Further, drugs are not paid under the Medicare physician fee schedule, and it is illogical to include them in calculating the SGR. Finally, the July 12 letter also discusses that CMS has the authority to revise its previous calculations of actual spending under the SGR by removing the costs of drugs back to the base period using this revised definition. Once CMS has revised calculations of actual spending back to the base period, it will have revised calculations of allowed spending, by definition, because the statute sets the base period allowed spending equal to the base period actual spending. This process would remove drugs entirely from both actual and allowed spending back to the SGR base period. CMS has demonstrated its authority to revise calculations of actual spending by actually revising spending to account for omitted codes and more complete claims data. This analysis was corroborated in a legal memorandum that we submitted to the Subcommittee in February 2005. It was drafted by Terry S. Coleman, a former Acting General Counsel of the U.S. Department of Health and Human Services, as well as a former Chief Counsel and Deputy Administrator of the Health Care Financing Administration.

CMS Should Remove Drugs from the SGR

In the past, some CMS officials have argued that including drugs in the SGR was necessary to counter-balance incentives for over-utilization in the drug reimbursement system. The AMA does not accept this premise. Certainly physicians are not administering chemotherapy drugs to patients who do not have cancer. Even if such incentives existed, however, they were surely eliminated by the reductions in payment for these drugs under the MMA. Pharmaceutical companies, not physicians, control the cost of drugs. Further, pharmaceutical companies and United States policy, not physicians, control the introduction of new drugs into the market place.

Drug expenditures are continuing to grow at a very rapid pace. Over the past 5 to 10 years, drug companies have revolutionized the treatment of cancer and many autoimmune diseases through the development of a new family of biopharmaceuticals that mimic compounds found within the body. Such achievements do not come without a price. Drug costs of \$1,000 to \$2,000 per patient per month are com-

mon and annual per patient costs were found to average \$71,600 a year in one study.

Further, between the SGR's 1996 base year and 2004, the number of drugs included in the SGR pool rose from 363 to 444. Spending on physician-administered drugs over the same time period rose from \$1.8 billion to \$8.7 billion, an increase of 365% per beneficiary compared to an increase of only 63% per beneficiary for actual physicians' services. As a result, drugs have consumed an ever-increasing share of SGR dollars and have gone from 3.7% of the total in 1996 to 10% in 2004.

This lopsided growth lowers the SGR target for real physicians' services, and, according to the Congressional Budget Office, annual growth in the real target for physicians' services will be almost a half percentage point lower than it would be if drugs and lab tests were not counted in the SGR. As 10-year average GDP growth is only about 2%, even a half percent increase makes a big difference. Thus, including the costs of drugs in the SGR pool significantly increases the odds that Medicare spending on "physicians' services" will exceed the SGR target. Ironically, however, Medicare physician pay cuts (resulting from application of the SGR spending target) apply only to actual physicians' services, and not to physician-administered drugs, which are significant drivers of the payment cuts.

Medicare actuaries predict that drug spending growth will continue to significantly outpace spending on physicians' services for years to come. In 2003, MedPAC reported that there are 650 new drugs in the pipeline and that a large number of these drugs are likely to require administration by physicians. In addition, an October 2003 report in the *American Journal of Managed Care* identified 102 unique biopharmaceuticals in late development and predicted that nearly 60% of these will be administered in ambulatory settings. While about a third of the total are cancer drugs, the majority are for other illnesses and some 22 medical specialties are likely to be involved in their prescribing and administration.

The development of these life-altering drugs has been encouraged by various federal policies including expanded funding for the National Institutes of Health and streamlining of the drug approval process. The AMA shares and applauds these goals. However, it is not equitable or realistic to finance the cost of these drugs through cuts in payments to physicians.

2. *Ensure that government-induced increases in spending on physicians' services are accurately reflected in the SGR target*

As discussed above, the government encourages greater use of physician services through legislative actions, as well as a host of other regulatory decisions. These initiatives clearly are good for patients and, in theory, their impact on physician spending is recognized in the SGR target. In practice, however, many have either been ignored or undercounted in the target. Since the SGR is a cumulative system, erroneous estimates compound each year and create further deficits in Medicare spending on physicians' services.

Effective January 1, 2005, CMS implemented the following new or expanded Medicare benefits, some of which have been mandated by the MMA: (i) initial preventive physical examinations; (ii) diabetes screening tests, (iii) cardiovascular screening blood tests, including coverage of tests for cholesterol and other lipid or triglycerides levels, and other screening tests for other indications associated with cardiovascular disease or an elevated risk for that disease, (iv) coverage of routine costs of Category A clinical trials, and (v) additional ESRD codes on the list of telehealth services.

As a result of implementing a new Medicare benefit or expanding access to existing Medicare services, the above-mentioned provisions will increase Medicare spending on physicians' services. Such increased spending will occur due to the fact that new or increased benefits will trigger physician office visits, which, in turn, may trigger an array of other medically necessary services, including laboratory tests, to monitor or treat chronic conditions that might have otherwise gone undetected and untreated, including surgery for acute conditions.

CMS has not provided details of how these estimates were calculated, and certain questions remain. Further, CMS reportedly does consider multiple year impacts and cost of related services, but the agency has not provided any itemized descriptions of how the agency determined estimated costs. Without these details, it is impossible to judge the accuracy of CMS' law and regulation allowances. For example, in reviewing the 2004 utilization and spending data, we found that utilization per beneficiary of code G0101 for pelvic and breast exams to screen for breast or cervical cancer had increased 10% since 2003, yet this benefit was enacted in BBA 1997 nearly eight years ago. Likewise, per beneficiary utilization of code G0105, colorectal cancer screening of a high-risk patient, also enacted in the BBA, was up 13%. These impacts should be taken into account in revising the 2005 and 2006 SGR.

CMS should also seek to identify other spending increases attributable to quality improvement programs and ensure that they, too, are reflected in the SGR law and regulation factor. For example, Medicare's Quality Improvement Organizations (QIO) have encouraged physicians to determine the left ventricular function of all patients with congestive heart failure, measured using a nuclear medicine test or an echocardiogram. Further, CMS revised the codes for end-stage renal disease services in 2004 to encourage four physician visits per month. From 2003 to 2004, consistent with CMS' intent, Medicare spending for the new ESRD codes rose 17% above 2003 spending for the old codes.

Spending due to all of the foregoing government initiatives should be reflected in the SGR.

3. *Ensure that the SGR fully reflects the impact on physician spending due to national coverage decisions*

When establishing the SGR spending target for physicians' services, the law requires that impact on spending, due to changes in laws and regulations, be taken into account. The AMA believes that any changes in national Medicare coverage policy that are adopted by CMS pursuant to a formal or informal rulemaking, such as Program Memorandums or national coverage decisions, constitute a regulatory change as contemplated by the SGR law, and must also be taken into account for purposes of the spending target.

When the impact of regulatory changes for purposes of the SGR is not properly taken into account, physicians are forced to finance the cost of new benefits and other program changes through cuts in their payments. Not only is this precluded by the law, it is extremely inequitable and ultimately adversely impacts beneficiary access to important services.

CMS has expanded covered benefits through the adoption of more than 80 national coverage decisions (NCDs), including implantable cardioverter defibrillators, diagnostic tests and chemotherapy for cancer patients, carotid artery stents, cochlear implants, PET scans, and macular degeneration treatment. While every NCD does not significantly increase Medicare spending, taken together, even those with marginal impact contribute to rising utilization. CMS has stated its view that it would be very difficult to estimate any costs or savings associated with specific coverage decisions and that any adjustments would likely be small in magnitude and have little effect on future updates.

We disagree, and strongly believe that CMS should make these adjustments in its rulemaking for 2006. **CMS already adjusts Medicare Advantage payments to account for NCDs, so it clearly is able to estimate their costs.** With respect to the magnitude of impact, as one example, CMS reported in January that the recent expansion of coverage for implantable defibrillators would make the devices available to some 500,000 people. In addition, CMS has provided us with data showing that 2004 Medicare Part B spending on PET scans was \$387 million, a 51% increase over 2003, and the agency has acknowledged that PET scans play an important role in diagnosing a number of diseases.

The AMA, along with 33 national medical organizations and state medical associations, contracted with the National Opinion Research Center (NORC) to estimate the costs of several NCDs to illustrate that it is possible to make such estimates and provide a sense of their magnitude. NORC's evaluation of the cost of the expanded coverage of photodynamic therapy to treat macular degeneration considered the cost of exams and fluorescein angiography tests to determine the appropriateness of treatment as well as treatment costs. NORC was also able to separate the costs that Medicare would have incurred due to local carrier coverage decisions from the expected costs associated with the NCD for treatment of the occult form of macular degeneration, for which Medicare prohibited coverage prior to the NCD. NORC conservatively estimates that the new coverage is increasing expenditures by more than \$300 million a year and could boost spending by more than twice that amount if used by all the eligible Medicare patients.

While the AMA strongly supports Medicare beneficiary access to these important services, physicians and other practitioners should not have to finance the costs resulting from the attendant increased utilization. **Accordingly, CMS should ensure that the impact on utilization and spending resulting from all national coverage decisions is taken into account for purposes of the SGR spending target.**

The AMA appreciates the opportunity to provide our views to the Subcommittee on these important matters, and we look forward to working with the Subcommittee

and CMS to develop a payment system for physicians that ensures patient access as well as payments that keep up with the costs of practicing medicine.

Chairman JOHNSON OF CONNECTICUT. Thank you very much, Dr. Armstrong, for that very clear evaluation of the response of physicians if we do not take action. Dr. Hedberg.

**STATEMENT OF C. ANDERSON HEDBERG, M.D., PRESIDENT,
AMERICAN COLLEGE OF PHYSICIANS, WINNETKA, ILLINOIS**

Dr. HEDBERG. I am Dr. C. Anderson Hedberg, President of the American College of Physicians. I offer the perspective of a practicing internist who has spent almost four decades caring for patients in the Chicago area, and as the leader of the Nation's largest specialty society. The College believes firmly that the medical profession has a responsibility to address documented gaps in quality. We support the goal of restructuring Medicare to provide incentives for improving quality. We have joined with others to create the Ambulatory Care Quality Alliance, AQA, a multi-stakeholder consensus group that reached agreement in May on a starter set of performance measures for ambulatory care. The AQA work groups are now working on developing additional measures, including efficiency measures, and on principles on data sharing and reporting for the next AQA meeting in September. There are several points I hope to leave with you.

First, the College appreciates Chairman Johnson's efforts to develop a Medicare value-based purchasing framework that includes repeal of the SGR formula. Second, we should be mindful of how such a program will play out in the real world of practicing physicians. Third, the initial steps toward value-based purchasing must be followed by a reexamination of the way that Medicare reimburses physicians.

The College understands that Chairman Johnson is working on a bill that includes several policies essential to successful implementation of Medicare quality improvement. First, quality improvement cannot take place in an environment where physician's fees are being cut. Addressing volume of services through careful analysis will be far more effective in ensuring appropriate care than using the flawed SGR. Second, quality measures should be developed by medical specialty societies, validated through a consensus-building organization such as the AQA, and phased in gradually.

The College applauds Chairman Johnson for her willingness to consider these important principles in her draft bill. As this legislation moves forward, I ask you to keep in mind how it will affect physicians and patients. One of my responsibilities is to travel around the country to learn from my colleagues. Internists, especially those in primary care practices, tell me that payments are not keeping up with practice expenses. Many are reluctantly considering closing their doors to new Medicare patients or even getting out of practice. They worry that pay-for-performance will be another unfunded mandate leading to more paperwork, more expense, less revenue and less time with patients.

They are concerned it could create adverse consequences for sicker and noncompliant patients. Medical students tell me that they do not see a future in primary care. We are already seeing a marked decline in the number of students choosing to be trained in general internal medicine.

If we do it right, value-based purchasing can help. Doing it right means assuring that Medicare reimbursement is sufficient to create positive incentives for performance improvement. It means providing funding commensurate with a physician's contributions to quality improvement. It means assuring that the data collection necessary to support quality improvement does not impose a heavy administrative burden on the physician. It means supporting the role played by primary care physicians, working with a team of subspecialty consultants and ancillary personnel, to assure that patients get the best possible care. Most importantly, it means that better quality must be the measure of success; cost savings should come as a result of quality improvement, but never at its expense.

Finally, the initial framework should be followed by a reexamination of Medicare payment policies. Paying physicians on a per-visit or per-procedure basis is not a model that supports continuous improvement in the care of patients with chronic diseases. The College advocates a new payment model to reward physicians for coordinating team-based care of patients with chronic diseases. We welcome the opportunity to discuss these ideas with the Subcommittee.

In conclusion, the College supports the goal of aligning Medicare's incentives with physicians' commitment to improve quality. As we do so, let us keep in mind two questions: Will we end up with a system that supports the physician-patient relationship by providing resources to help physicians improve care of their patients? Or will it be a system that undermines that relationship resulting in more paperwork, more expense, less revenue, and less time with patients. As a life-long fan of the Chicago Cubs, I am, by nature, an optimist. I believe that when good people work together, good things will happen. However, my optimism is tempered by the knowledge that hoping for the best is not enough. Value-based purchasing is a promising idea. Let's make sure we do what is needed to get it right the first time, be aware of the risk of unintended consequences and be prepared to make corrections if needed. I appreciate your attention, and I will be pleased to answer any questions.

[The prepared statement of Dr. Hedberg follows:]

Statement of C. Anderson Hedberg, M.D., President, American College of Physicians, Winnetka, Illinois

The American College of Physicians (ACP), representing over 119,000 doctors of internal medicine and medical students, is pleased to provide testimony on the issue of value-based purchasing for physicians under Medicare. This testimony is provided for the July 21, 2005 hearing held by the Health Subcommittee of the United States (U.S.) House of Representatives Ways and Means Committee. Our testimony will focus on the following areas:

1. The steps the College is taking to lay the groundwork for value-based purchasing by helping internists understand how to incorporate proven quality improvement methods in their practices and to provide them with the technological capacities to support quality improvement.

2. The College's leadership role in selecting performance measures for ambulatory care that could be used in a Medicare value-based purchasing program as well as in other quality improvement programs.

3. The College's views on how to design a legislative framework for value-based purchasing that will support and strengthen the ability of physicians to engage in continuous quality improvement.

4. The College's views on the importance of carefully assessing the impact of provider-based purchasing on practicing internists and the relationships they have with their patients.

5. The College's views on the need to engage in a comprehensive re-examination and restructuring of Medicare payment policies to support quality improvement, particularly for patients with multiple chronic diseases.

LAYING THE GROUNDWORK FOR VALUE PURCHASING

ACP firmly believes that the medical profession has a professional and ethical responsibility to engage in activities to continuously improve the quality of care provided to patients. We therefore commend this committee for addressing quality in the Medicare program through the concept of value-based purchasing. ACP was among the first medical professional organizations to support the concept of linking payments to physician performance on evidence-based measures. We recognize, however, that pay-for-performance cannot by itself lead to quality improvements if physicians in practice lack the capabilities to incorporate proven quality improvement methods in their practices. Accordingly, the College is engaged in *over forty projects* to improve the quality of care provided to patients, including two new grant-funded programs to improve the care of patients with diabetes and to implement quality measures for the frail elderly.

ACP is also actively engaged in initiatives to develop the health information technology infrastructure to support quality improvement. We serve on the boards of the Certification Commission for Health Information Technology and the Electronic Health Initiative; co-chair the Physicians Electronic Health Record Coalition (PEHRC), and are actively involved in the Connecting for Health initiative. We have developed recommendations for legislation to provide initial funding and sustained reimbursement support to help clinicians, particularly those in small practices, acquire and use HIT to support their participation in quality improvement projects. The College has joined with other stakeholders to submit proposals in response to Secretary Leavitt's requests for proposals on standard harmonization and certification of electronic health records.

The College is also committed to providing practice internists with practical tools to help them improve quality. ACP's Physicians Information and Education Resource (PIER) provides ACP members—at no cost to them—with access to “actionable” evidence-based guidelines at the point of care for over 300 clinical modules. PIER has also been incorporated into several electronic health record systems. PIER is currently in the process of aligning its evidence-based content to support a starter set of measures selected by the Ambulatory Care Quality Alliance (AQA). PIER is also creating paper order sets that imbed such quality measures in the order set, so that physicians who have not made the transition to electronic health records could still rely on PIER content to support their participation in performance measurement initiatives.

ACP's PracticeManagementCenter has developed resources to help internists go through the decision-making process on electronic health records and is in the process of working with other entities in the College to provide internists with tools and best practices to help them redesign their office processes to improve health care quality.

ACP is also directly involved in supporting several federal demonstration projects to improve quality. We are directly involved in implementation of the Chronic Care Improvement Program/Medicare Health Support pilots in Mississippi and Pennsylvania as authorized by Section 721 of the Medicare Modernization Act, working with the awardees to develop mechanisms to support physicians' roles in coordinating and improving care of patients with diabetes and congestive heart failure. The College has also endorsed the Doctor's Office Quality Information Technology (DOQ-IT) demonstration project and is working with the American Health Quality Association to support the 8th Scope of Work.

Through these and other initiatives, the College is laying the groundwork for Medicare value-based purchasing by educating internists on how to incorporate performance measurement and improvement in their practices, by providing them with evidence-based clinical decision support, by partnering with others to develop the health information technology infrastructure to support quality improvement, by providing internists with practical tools to help them redesign office processes to im-

prove quality, and by gaining first-hand knowledge from federal demonstration projects and pilot programs on how to incorporate quality improvement in the Medicare program.

SELECTING PERFORMANCE MEASURES FOR AMBULATORY CARE

ACP's long-standing commitment to evidence-based medicine and continuous quality improvement is also evidenced by our active involvement in the Ambulatory Care Quality Alliance (AQA), which in May 2005 took a major step toward improving the quality of the U.S. health care system by selecting a "starter set" of 26 clinical performance measures for the ambulatory care setting. (We ask that the starter set of measures, which is attached to this statement, Attachment 1, be recorded in the official record on this hearing.) ACP is one of four original organizations that organized and convened the first AQA meeting in the fall of 2004 (the other three co-conveners are America's Health Insurance Plans, the American Academy of Family Physicians, and the Agency for Healthcare Research and Quality) and we continue to serve on its steering committee.

The AQA, a national consortium of large employers, public and private payers, and physician groups, aims to improve health care quality and patient safety through a collaborative process in which key stakeholders agree on a strategy for measuring, reporting and improving performance at the physician level. The AQA also works to promote uniformity in order to provide consumers and purchasers with consistent information and to reduce the burden on providers. This approach is similar to the Hospital Quality Alliance, which involved a broad array of stakeholders with the goal of producing a standardized set of measures for inpatient care.

The AQA's starter set of ambulatory care measures is intended to provide clinicians, consumers and purchasers with a set of quality indicators that may be utilized for quality improvement, public reporting and pay-for-performance programs. The rationale behind the measurement starter set is to allow physicians to get used to tracking a few simple performance goals, while more sophisticated measurements and implementation guidelines are developed. While the College and other medical groups would prefer to take an evidence-based approach by waiting for results from pay-for-performance pilots and demonstrations, the market simply will not wait. Instead, ACP is confident that the AQA's starter set of measures represents the first of several generations of increasingly sophisticated performance measurement sets that can be used with confidence to measure quality of care in the ambulatory area.

AQA's uniform starter set comprises prevention measures for cancer screening and vaccinations; measures for chronic conditions including coronary artery disease, heart failure, diabetes, asthma, depression, and prenatal care; and, two efficiency measures that address overuse and misuse. Except for the two efficiency metrics, the AQA limited its review to those measures that are currently under review by the National Quality Forum.

ACP, and the other members of the consortium, worked hard to ensure that the initial set of measures relied principally on administrative data that is readily available for most practices, thereby reducing the administrative burden of having to extract information from medical records. In addition, they ensured that the starter set met the standards of scientific validity, feasibility, and relevance to physicians, patients and purchasers. AQA participants are also beginning to seriously address the complex issues associated with creating the infrastructure for performance reporting. The AQA is also working on a model for aggregating, sharing and stewarding data that maintains appropriate restrictions on privacy and confidentiality, as well as principles for reporting information to providers, consumers and purchasers.

ACS'S VIEWS ON A LEGISLATIVE FRAMEWORK FOR VALUE BASED PURCHASING

The College recently released a detailed draft proposal for a legislative framework for Medicare that linked financial incentives to performance quality, which was shared with the staff of the Ways and Means Health Subcommittee and other key health committees. ACP, along with other national organizations representing primary care physicians, also sent a letter to Congressional leaders that affirmed our joint commitment to work with Congress to develop an effective legislation on framework for Medicare quality improvement (Attachment 2). There are several key elements, as outlined in our recommended framework and in the joint letter that we believe should be incorporated into any legislation to establish a Medicare value-based purchasing program.

THE USE OF AQA PRINCIPLES IN A VALUE-BASED PURCHASING SYSTEM

First, it is critical that any value-based purchasing system that links physician reimbursement to evidence-based performance measures follow principles similar to those that guided the AQA process. For one, there must be an explicit role for a consensus-oriented multi-stakeholder group to select and validate quality and efficiency measures for clinical conditions and to evaluate issues of feasibility and meaningful data collection. It is absolutely necessary that this process be transparent. It is also important that adequate feedback be provided on why certain measures are not selected in order to allow the measures to be further refined and resubmitted and to ensure that the scientific evidence behind the measure, administrative feasibility of data collection, and other elements are well considered. This multi-stakeholder group must also have strong representation of national physician specialty societies in the leadership and governing board structure of the entity. The leadership of ACP and others in the AQA process has been essential for the credibility of the process, and we would hope to maintain a comparable leadership role in any new entities created by legislation.

THE USE OF EFFICIENCY MEASURES

Second, ACP supports evidence-based clinical performance measures in a value-based purchasing program that address overuse, underuse and misuse, but we are concerned that efficiency measurement will be driven by statistical economic profiling rather than a review of the clinical evidence. Appropriate quality measures take into account evidence to support or not support particular interventions based on evidence-based guidelines on overuse and underuse rather than just using a statistical profile of cost and volume. A strict volume/cost analysis derived from claims data for utilization patterns will not provide accurate data on quality or cost and should not be used to determine payments based on performance. Comparisons of utilization patterns are not a substitute for true efficiency measures that consider the quality *and* costs associated with treatment of particular conditions.

It is unlikely that a risk adjustment methodology will soon be developed that can adjust for all problems related to reporting on the efficiency of individual physicians in providing care to patients based on a comparative analysis of claims. Statistical comparisons need to take into account not only the need to risk adjust for severity of illness, but also for socioeconomic factors such as income, race, culture, and language proficiency, which significantly influence a patient's willingness to trust the health care provider and comply with recommended treatments. Without such adjustments, physicians who see a disproportionate number of low-income or racial/ethnic minority patients would be penalized for factors outside their control and dissuaded from participating in quality improvement programs. Quality improvement programs should not inadvertently exacerbate health disparities or create other unintended consequences for patients or physicians who have sicker patient populations as well as noncompliant patient populations.

PUBLIC REPORTING

Third, while ACP understands that public reporting *potentially* provides patients and purchasers with a more informed choice about physicians; public reporting can create severe adverse unintended consequences for patients if not done correctly. Studies show that public reporting can create unintended incentives for physicians to avoid higher risk or non-compliant patients that will result in their public report being less favorable. This is particularly a concern for patients with certain ethnic, racial, socioeconomic or cultural characteristics that make them less compliant with recommended treatments, less likely to see a physician for preventive care, and less likely to take prescribed medications. Sufficient risk adjustment and methodologies to reduce the risk that public reporting will create such unintended consequences are essential before physician-specific quality data are released to the public. In addition, many patients function at a health literacy level that makes it difficult for them to understand basic medical information given to them by their clinician, never mind comparative data on quality. More studies are needed on whether patients benefit more from seeing reports on whether or not their physician surpasses a minimum threshold of quality improvement or from ranking of physicians based on quality indicators. For this reason, the College has advocated for a well-designed demonstration project on public reporting of quality improvement data.

ACP agrees with the Medicare Payment Advisory Commission (MedPAC) recommendation that physician performance profiling first be shared confidentially with physicians as an educational tool. Furthermore, ACP believes that when public reporting is implemented, physicians should be allowed to not only review data before it is released but to appeal it to an independent reviewer that would be charged

with resolving concerns relating to the public report in a way that assures that all information that is reported is unbiased and accurate. Physicians should also have the right to have their comments on the report included along with the data that are reported.

A PHASED IN APPROACH

Fourth, ACP strongly supports a phased in approach to valued-based purchasing linked to physician performance.

The College believes that a Medicare value based purchasing program should start with pay for achieving basic structural measures (pay-for-reporting), followed by payment for participating in quality improvement programs that use evidence-based clinical measures (pay-for-participation), followed by pay for achieving quality gains as measured by such evidence-based measures (pay-for-performance):

Stage One: Pay-for-Reporting

ACP recommends Medicare institute a *pay-for-reporting* initiative beginning in 2007 using a structure along the lines of the MedPAC recommendation to begin paying for structural measures (i.e., assessing whether the provider has the capability to deliver quality care) consisting of quality-enhancing functions and outcomes facilitated by the use of information technology (HIT) and other improvements. A process should be created for physicians to begin reporting during the calendar year that they have the structural capabilities to support quality improvement. Additional payments would then be allocated to physicians, during the same calendar year, who met the pay-for-reporting requirements.

Stage Two: Pay-for-Participation

ACP recommends that Medicare should institute a more robust and voluntary *pay-for-participation* program beginning in 2008 that would allocate additional payments (i.e., in addition to and separate from the annual Medicare fee schedule update) to physicians on a *graduated* basis who agree to voluntarily participate in quality improvement programs that use *evidence-based measures* for clinical conditions that have the greatest potential to yield the greatest quality improvements and potential system-wide savings stemming from improved quality. During the pay-for-participation phase, payment should be based on documentation of participation in such programs, not on how well the individual physician does in meeting the actual measures.

Such additional payments should be graduated and proportionate to the level of commitment on the part of the physician to participating in approved performance measurement programs. Because participation in performance measurement programs involves substantial costs (for HIT, data collection and reporting) and time commitment from physicians and their staffs, pay should increase proportionately based on the number of dimensions of care being measured, the number of measures, the time and costs associated with documenting performance based on the measures, and the level of HIT acquired by the practice to support participation in approved quality improvement programs. For example, physicians who just meet the basic structural measures as outlined in Stage One should receive a lower bonus payment than physicians who are participating in programs that use multiple evidence-based measures designed to improve care of patients with high cost chronic diseases. A graduated payment structure would create stronger incentives for physicians to participate in performance improvement programs (and for specialties to develop evidence-based measures of performance) than paying all physicians the same amount regardless of their level of commitment to such programs.

Stage Three: Pay-for-Performance

ACP recommends that HHS be directed to consult with medical professional societies and other stakeholder groups on development of a *pay-for-performance* program that would be initiated no earlier than calendar year 2010. The pay-for-performance program would provide graduated bonus payments to physicians who demonstrate success in meeting evidence-based performance measures.

ASSURING SUFFICIENT FUNDING

Fifth, the College believes it is essential that Congress assure adequate funding for the value-based purchasing program, starting with repeal of the sustainable growth rate (SGR) formula. The need for a long term solution for updating the Medicare physician fee schedule is underscored by continued projections of deep cuts. Despite Congress' success in preventing cuts from taking effect in 2003–2005, payment reductions of over 4 percent next year and 26 percent from 2006–2011 are forecast. The underlying flaw of the SGR formula is the link between the perform-

ance of the overall economy and the actual cost of providing physician services. The medical needs of individual patients are not related to the overall economy.

ACP strongly urges Congress to pass legislation to replace the SGR formula once and for all. In the future, annual updates in Medicare payments should instead be linked to increases in the actual costs of medical practice. ACP supports basing updates on the projected change in input prices less an adjustment for productivity growth, as has been recommended by MedPAC. Applying this methodology would result in a 2.7 percent increase in the fee schedule conversion factor next year and a similar increase in 2007 (currently projected to be 2.4 percent).

ACP also supports the MedPAC recommendation that volume should be managed through a process in which the reasons for each significant volume increase are identified, and specific measures be taken either administratively or through legislation to control those increases not related to improvements in quality of care. Addressing volume through careful analysis and consideration, with appropriate policy interventions, will be far more effective in assuring that appropriate care is provided than the flawed SGR.

APPLYING ACP'S RECOMMENDED FRAMEWORK TO CHAIRMAN JOHNSON'S PROPOSED DRAFT LEGISLATION

The College understands that Chairman Johnson will be introducing a value-based purchasing bill. Based on our understanding of what the bill likely will include, the College anticipates that the overall approach will be consistent with the College's recommendations, as summarized above.

We are very pleased that the bill will likely include repeal of the SGR and will base future updates on the Medicare Economic Index, minus a productivity factor, as recommended by MedPAC. By doing so, it recognizes that successful implementation of Medicare quality improvement cannot take place in an environment where physician fees are being cut. We also understand that the proposal will reduce the update by a yet-to-be-defined percentage for physicians who decline to participate in the performance measurement and reporting program.

Although the College would prefer that new money be provided to support the value-based purchasing program, we understand that budget constraints may limit the initial funding to an amount that is no higher than levels recommended by MedPAC. However, we urge the subcommittee to establish a floor on the annual updates in 2006, 2007, and 2008, so that all physicians receive a positive update. The College specifically recommends that all physicians receive an update that is no lower than 1.5 percent, and that an additional amount be provided to those who participate in the performance reporting and measurement program, up to the full amount recommended by MedPAC.

We also recommend that the bill give HHS the authority to weigh the performance-based payments so that those physicians who engage in reporting data using multiple measures can qualify for higher payments than those who report on only a few structural measures. For instance, an internist who participates in a program that uses the AQA starter set will be obligated to report performance for as many as 24 separate measures (the two measures relating to pediatric care are not applicable to most internists), requiring a substantial investment of time and practice resources. Unless performance-based payments are commensurate with effort, physicians will be discouraged from doing anything more than the most elementary and basic measurement and reporting required to qualify for the full update.

We also understand that the bill likely will call for a gradual phase-in of the measures, starting with *pay-for-reporting* of structural and quality measures before Medicare begins paying physicians on the measures themselves, similar to the step-wise approach recommended by ACP.

We also understand that the proposal will likely recognize the critical role played by medical specialty societies in *developing* measures that are then *validated* through a consensus building organization involving multiple stakeholders. As noted above, our experience with the AQA demonstrates that a consensus process, with physician leadership, can result in getting "buy-in" from physicians, purchasers, payers, and consumers on a practical set of measures.

The College is concerned that the value-based purchasing program for physicians is funded totally out of savings in Medicare Part B and in reductions and set asides from the conversion factor paid to physicians. Value-based purchasing should recognize physicians' collective and individual contributions to achieving system-wide savings through better quality. Accordingly, we urge that a provision be included in the legislation directing the Secretary to develop a methodology, in consultation with the Medicare Payment Advisory Commission (MedPAC), the Practicing Physician Advisory Council (PPAC), national membership organizations representing practicing physicians and other appropriate experts to increase the total pay-for-

quality bonus pool available to physicians based on evidence that the value-based purchasing program for physicians has resulted in system-wide Medicare savings. Such savings should include savings in Medicare Part A, such as from preventing unnecessary hospitalizations caused by complications. The methodology should allow for individual physicians to share in such system-wide savings that are attributable to their participating in performance measurement and improvement programs and physician-guided chronic care coordination. The methodology and recommendations should be reported to Congress no later than December 30, 2006. Legislation should be required to institute the methodology.

In summary, based on our understanding of the overall direction that Chairman Johnson is likely to propose in her bill, the College expects that we will be able to support the legislation, although we hope to have the opportunity to continue to recommend ways to make the framework as effective as possible, including assuring that the overall funding for the program is sufficient to result in the desired changes. We commend Chairman Johnson for her leadership on this issue and her responsiveness to the views offered by ACP and other medical organizations on how to structure the legislation.

ASSESSING THE IMPACT OF VALUE-BASED PURCHASING ON PRACTICING INTERESTS

As Congress moves forward on developing a Medicare value-based purchasing program, we believe that it is essential that Congress be mindful of the potential impact on practicing internists and potential unintended adverse consequences.

Internists are encountering an aging population that requires substantial care and support as a result of an increasing number of chronic conditions. These practitioners, who provide the predominance of care to our Medicare beneficiaries, are also aware of the significant gaps in health care quality as reflected by the landmark Institute of Medicine report, *Crossing the Quality Chasm*. Our members are primed to meet this challenge to improve healthcare quality, safety and access, and make the necessary changes in their practices to better meet the needs of their patients. These changes include the increased need to coordinate care, to reach out to patients to ensure they are following their treatment regimens and to implement available health information technology (e.g. electronic health records, patient registries, e-prescribing, clinical decision support tools) into their daily office routine. These changes are difficult to make in an environment characterized by the specter of payment cuts throughout the foreseeable future. Repealing the SGR is an essential first step, but by itself, will not stabilize the economic environment for many internists sufficiently to allow them to provide high quality care and engage in continuous quality improvement.

For most primary care physicians, Medicare payments are not keeping up with their practice expenses. Many are reluctantly considering closing their doors to new Medicare patients or even getting out of practice. They worry that pay-for-performance will be another unfunded mandate, leading to more paperwork, more expense, less revenue, and less time with patients. They are concerned that it could create unintended adverse consequences for sicker and non-compliant patients. It is not just physicians in practice who express these concerns. Medical students do not see a future in primary care, as evidenced by the marked decline in recent years in the number of physicians who are being trained in general internal medicine and family practice.

Done correctly, value-based purchasing can help. By doing it right, it means assuring that Medicare money is sufficient to provide updates based on inflation and to create positive incentives for performance improvement. It means providing rewards commensurate with an individual physician's commitment of time and resources to support quality improvement. It means lifting up all boats rather than leaving some to founder. It means assuring that the data collection does not impose a heavy administrative burden. It means supporting the crucial role played by primary care physicians, working with a team of skilled subspecialist consultants, in assuring that patients get the best care possible. Most importantly, it means that better quality must be the measure of success; cost savings should be the *result* of quality improvement but never at its expense.

Primary care is at an important crossroads at this time. Fewer physicians are choosing to enter into primary care and those in the profession are expressing increased dissatisfaction. Primary care can be re-energized to the extent this current pay-for-quality discussion in Congress results in an improved payment system that adequately rewards physicians for providing the coordinated quality care required and implementing necessary practice changes. If the discussion results in a pay-for-quality system perceived as punitive by our practitioners, replete with additional unfunded demands and unproductive "time stealers" from the physician and their

staff, it can serve as the straw that figuratively breaks the camel's back and leads to an unfortunate acceleration in the shortage of primary care practitioners. Reduced access to primary care physicians would be very detrimental to our Medicare beneficiaries. The majority of Americans have demonstrated a preference for a sustained relationship with a primary care provider and studies indicate that a continuous patient-physician relationship correlates with patient satisfaction, improved health, positive outcomes, reduced malpractice litigation, as well as reduced emergency department use and reduced health care costs per patient.

RE-EXAMINING AND REFORMING DYSFUNCTIONAL PAYMENT POLICIES

Finally, the initial framework should be followed by a comprehensive re-examination of Medicare payment policies. Unfortunately, Medicare payment policies are based on the way that care was provided in 1965—not the way it is being delivered today *or will be in the future*. When Medicare was created in 1965, patients generally were treated only when sick (acute condition); there was little or no emphasis on prevention and coordination; care was based on doctor's best judgment as informed by continuing medical education and journals but not on scientific guidelines; and payment was made only for work involved in a specific visit or procedure, not on results. Medical care today and in the future will involve treating patients' chronic conditions, not just acute illnesses; preventing and managing illness rather than just treating disease; care will be rendered by coordinated teams of health professionals; clinical judgment will be informed by evidence-based clinical decision support; and the results of care will be rewarded.

The College specifically advocates a new payment model to reward physicians for coordinating team-based care of patients with chronic diseases in a way that will result in better quality and potential cost-savings, including the work that falls outside of the traditional office visit, such as working with family caregivers on helping patients manage their own diseases and arranging for team-based care involving other health professionals. This "patient-centered, physician-guided" chronic care model is based on the work of Ed Wagner, MD, FACP and it provides physicians designated by beneficiaries as their "medical home" with payments based on their ability to effectively manage and coordinate care. We welcome the opportunity to discuss our ideas with the subcommittee.

CONCLUSION

In conclusion, the College supports the goal of aligning Medicare's incentives with physicians' commitment to improve quality and we commend Chairman Johnson for her leadership on developing a practical approach to value-based purchasing that includes repeal of the SGR. As Congress moves forward on the legislation, we ask that you keep in mind two critical questions: will we end up with a system that supports the physician-patient relationship by providing resources to help physicians improve care of their patients? Or will it be a system that undermines that relationship, resulting in more paperwork, more expense, less revenue, and less time with patients? The College is dedicated to working with the subcommittee to assure that it is the first question, not the second, which gets a resounding yes from physicians and their patients.

Chairman JOHNSON OF CONNECTICUT. Thank you very much. Dr. Kassirer.

STATEMENT OF JEROME P. KASSIRER, M.D., PROFESSOR, TUFTS UNIVERSITY SCHOOL OF MEDICINE, BOSTON, MASSACHUSETTS

Dr. KASSIRER. Thank you, Madam Chairman. I am Jerome Kassirer, a physician and professor with medical school appointments at Tufts University in Boston and Case Western Reserve University in Cleveland. I am a former editor of the New England Journal of Medicine and author of *On the Take, How Medicine's Complicity with Big Business Can Endanger Your Health*. I am representing no institution or no medical professional organization. With respect to financial incentives, I will assert that the medical

profession has become excessively dependent on the largesse of the pharmaceutical industry, that these financial connections have a negative influence on the quality and cost of patient care and the trust of the public, and that the profession's response to these threats has been inadequate.

American doctors train many years, many go into massive debt to become physicians, and then work very hard in practice. There is no other country where I would prefer to get care for myself or my family. Our medical institutions are respected around the world. Like the rest of us, however, doctors respond to financial incentives. I need not remind any of you that what a struggle it has been to try to eliminate self-referral of patients to privately-owned health care facilities. The magnitude of self-referral and the professional incentives of value-based purchasing, in my opinion, pale compared to the enormous financial incentives generated for doctors by the pharmaceutical and device industries. By themselves, the drug companies are powerless, but they have willing accomplices, namely, many thousands of physicians. We do not need to look far back for striking examples of medical decisions that may have been influenced by perverse financial incentives.

A few weeks ago a U.S. Food and Drug Administration (FDA) panel recommended that Vioxx return to the market by a narrow margin despite its cardiac toxicity. Nine of the 10 panel members who had financial arrangements with industry voted in favor. Panel members with no conflicts voted 12 to 8 against. The drug's return would have been vetoed if none of the conflicted members had voted. Recently State Medicare managers became alarmed about the burgeoning use of the drug Natrecor. The drug had been approved for patients with acute episodes of heart failure, but instead, it is being given by infusion routinely and repeatedly in many doctors' offices, despite the opinion of experts that routine use of the drug has no benefit, and that the drug causes kidney damage and even death.

The incentive for each office infusion is about \$600. The issue here is similar to the cancer drugs discussed by Dr. McClellan. Last week, the Wall Street Journal reported that in 2004, the number of pharmaceutical company-sponsored meetings and talks that featured doctors as speakers had grown to nearly 240,000, a four-fold increase over the previous 6 years. There is a natural tendency for a speaker to reciprocate for a \$1,000 or \$2,000 honorarium by favoring a company's products, including their off-label uses. We have learned that if they criticize the company's products, their tenure as a speaker will be short. A year ago, a practice guideline on cholesterol issued by three prestigious organizations unveiled treatment recommendations so stringent that millions of Americans at risk for heart disease would have had to start taking expensive statin drugs.

As it turned out, six of the nine panel members who wrote the recommendation had been on the payrolls of three to five of the companies that manufacture statins. Flaws in research study design, bias in reporting of research, and risk to patients in clinical trials constitute another serious consequence, and a constant promotion of expensive drugs with free samples heightens the cost. If

anything, companies are tightening and extending the connections, increasingly recruiting physicians to their marketing efforts.

Leaders of the profession have done little to counter a trend in which the profession has become increasingly beholden to industry. Most professional organizations have published ethical guidelines, but they allow physicians to receive gifts and meals and are silent on the appropriateness of physicians as consultants on marketing, promotion of off-label drugs and membership on speakers bureaus. These activities, in my view, should be eliminated. The public, and many in the profession, are becoming increasingly exercised about the profession's tilt to industry. Extracting medicine completely from this financial magnet may be difficult, but I believe it must start. If the profession fails to act, I believe Congress should.

[The prepared statement of Dr. Kassirer follows:]

Statement of Jerome P. Kassirer, M.D., Professor, Tufts University School of Medicine, Boston, Massachusetts

I am Jerome P. Kassirer, M.D., Distinguished Professor at Tufts University School of Medicine in Boston, Adjunct Professor of Medicine and Bioethics at Case Western Reserve University School of Medicine in Cleveland, former Editor-in-Chief of the *New England Journal of Medicine*, and sole author of the book, "On The Take: How Medicine's Complicity With Big Business Can Endanger Your Health," published nine months ago by Oxford University Press. I represent no institution or no medical professional organization. I am here to offer the findings of my research into the consequences of perverse financial incentives in medicine. I will assert that the medical profession has become excessively dependent on the largesse of the pharmaceutical industry, that these financial connections have a negative influence on the quality and cost of patient care and the trust of the public, and that the profession's response to these threats has been inadequate. I appreciate the opportunity to share these concerns with you.

American doctors train for many years, and many go into massive debt to become physicians. They then work long hours, struggling in a complex health care delivery system to reduce the burden of illness. There is no other country where I would prefer to get care for my family or myself. Our physicians, hospitals, medical centers and medical professional organizations are respected around the world.

But doctors are human, and like the rest of us they respond to financial incentives. I need not remind any of you what a struggle it has been to try to eliminate physician self-referral of patients to privately owned health care facilities. But the magnitude of self-referral pales compared with the enormous financial incentives generated for physicians by the pharmaceutical, biotechnology, and medical device industries.

As you watch the pharmaceutical ads on television, you are likely to conclude that the drug industry is spending most of its promotional money to get you to ask your doctor whether Cialis or Nexium is right for you, but in fact, over 80% of the more than \$20 billion yearly advertising expenses of the industry is directed at doctors and other health care professionals. There is nothing fundamentally wrong with advertising products, but when financial incentives yield inappropriate or dangerous care, when they inordinately raise the cost of care, and when their effect is to damage the trust of patients in the profession, they have gone too far.

It is too easy to lay the blame on the companies, though there is plenty of blame to go around. By themselves, the companies are powerless, but they have willing accomplices, namely thousands of physicians in academic medical centers and in private practice. We need not delve into ancient history to find striking examples in which questionable or flawed medical decisions have been attributed to financial incentives from industry. A few weeks ago we learned that an FDA panel recommended to allow Vioxx to return to the market by a narrow margin despite its recognized cardiovascular toxicity. The 10 panel members who had financial arrangements with industry voted 9:1 to bring the drug back; panel members with no such arrangements voted 12: 8 against. If none of the conflicted members had voted, the drug's return would have been rejected. In the past few weeks we've also heard that state Medicare managers have become alarmed about the burgeoning use of Natrecor, a drug estimated to reach sales of almost \$700 million this year. The drug was approved by the FDA for patients with acute episodes of heart failure, but it is widely being given by infusion routinely and repeatedly in many doctors' offices

instead. The financial incentive for routine office use? A Medicare payment for each visit of \$500—\$600. Unfortunately, according to expert cardiologists, there are no data that routine use is beneficial, and there is increasing evidence that the drug damages the kidneys and may even increase the death rate. Despite this information, many physicians continue to prescribe the drug.

This is as good a time as any to explore physician motivation, and the continued use of Natrecor despite lack of evidence of efficacy and in the face of toxicity provides an excellent example. Heart failure is a common condition, and infusing only one patient a day could yield \$150,000 a year to a physician's bottom line. The first and most obvious conclusion is that the doctors who use the drug by routine infusion are motivated by greed. Perhaps some are, but this explanation is much too simplistic. Some physicians probably first use the drug on one or two patients, were impressed with the results, and because they are free to use any drug off-label, began to use it on others. The reimbursement for the procedure may have played no role in their decision, or at best it had only a subconscious influence. The problem with conflict of interest is that we are unable to fathom financially conflicted individuals' motivations; psychologists tell us that people themselves might not even know their motives. What we do know is that a powerful financial incentive exists to exploit the reimbursement system.

Influence on FDA advisory boards and the kinds of perverse incentives in day to day practice represent only a small part of the ways that physicians' financial involvement with industry can affect clinical care and costs. Last October I reported in the Washington Post about efforts of pharmaceutical companies to enlist physicians in their marketing efforts. Drug companies are precluded by the FDA from promoting off-label uses of drugs, but physicians have no such prohibitions, and many, through their industry interactions, are in essence becoming the modern drug reps. Industry implements physician marketing by a number of approaches. One is the funding of product—promoting front organizations such as the National Anemia Action Council and the Council for Hormone Education. These organizations are funded by industry and are comprised of many financially conflicted physicians. Prominent academics head them, and they hire academic physicians to collect and edit medical content, which is distributed with the avowed purpose of educating doctors and improving patient care. The material looks like medical content that doctors might find in journals, but it does not undergo peer review. Although some of the content may be worthwhile, some is overtly biased in favor of the sponsors' products. Industry cannot do this kind of marketing without the willing partnership with doctors. I am quick to point out that off-label drug use by physicians is not only legal, but in some instances a drug approved only for one particular condition is found to work quite well for others. At the same time, off-label use can have disastrous effects, especially if the drug is widely used and only shows serious toxicity after widespread use. Our experiences with phen-fen is a sorry reminder of this scenario.

Industry-funded educational lectures constitute still another major source for flawed drug use and increased expense, and the number of physicians appointed to drug company speaker's bureaus is growing. Last week the Wall Street Journal reported that in 2004, the number of pharmaceutical company-sponsored meetings and talks that featured doctors as speakers had grown to nearly 240,000, a four fold increase over the previous six years. At present, industry pays for well over half of the expense of doctors' continuing medical education; virtually all the continuing education departments in hospitals, medical centers, and medical schools rely on drug-company funding. Drug companies also pay individual doctors to speak at national meetings, medical center conferences, and restaurant back rooms. Companies recruit speakers known to be sympathetic to their products and give them further training. Although the speakers are usually told that they are not obliged to mention the sponsor's drugs, there is a natural sense of obligation to reciprocate for the \$750 to \$4,000 honorarium. Some physicians say they feel subtle pressure to promote products because they want to stay on the speakers list; others hold back from criticizing companies whose fees they receive. Harking back to the issue of the cardiovascular complications of Vioxx, we learned that several physicians on Merck's speaker's bureau were threatened by a Merck senior vice president to stop telling their audiences about the risks of Vioxx; big brother had been listening in on their lectures. Even when speakers honestly believe that they are not promoting products, the presence of drug company representatives and drug brochure handouts at a dinner lecture exposes the feigned attempt at objectivity. There is little doubt that company-sponsored lectures increase the use of drugs mentioned in the lecture; given that the drugs mentioned are usually the newest, most expensive agents and certainly not the generics, the physician lecturers are contributing to the increased, and increasing, cost of medical care. Whether the recent attempts of the organiza-

tion responsible for accrediting physicians' educational programs, the Accreditation Council for Continuing Medical Education (ACCME) to sanitize speakers' presentations by applying increasingly stringent regulations on financially conflicted speakers will succeed is not yet known.

Even more worrisome than the effect of bias on the part of individual speakers is the potential effect of financial conflict of interest in the development of clinical practice guidelines, the professional society advice to practicing doctors about the treatment of certain conditions. Similar to the broad influence of FDA decisions on drug use, a statement from the American College of Physicians or the American Neurological Association on the treatment of migraine, for example, would have a major impact on the use of the drugs recommended in a guideline report. Both the public and the profession paid close attention one year ago when a clinical practice guideline issued by three prestigious organizations, the American Heart Association, the American College of Cardiology, and the National Institutes of Health, unveiled guidelines for cholesterol levels so stringent that millions of Americans at risk of heart disease would have to take costly statin drugs to meet the proposed low limits. What the three organizations didn't reveal was that most panel members who helped write the recommendations had financial ties to the pharmaceutical companies that stood to gain enormously from increased use of statins. The extent of the connections was stunning: Of the nine members of the panel that wrote the guidelines, six had each received research grants, speaking honoraria or consulting fees from at least three and in some cases all five of the manufacturers of statins; only one had no financial links. In response to criticism of the panel composition, the Heart Association said that the policy had been reviewed by many others, not just formulated by nine people, yet they did not disclose the conflicts of any other reviewers. Even if they had, such disclosures would tell us little about the objectivity of the statin recommendations.

Professional societies rely heavily on financial support from the drug industry, and nowhere are society-industry connections more evident than at yearly national meetings. Companies can purchase attendance lists replete with the attendees' demographic information; they can pay for cocktail parties, free e-mail kiosks, tote bags, meals, trinkets, and buses to ferry people from hotels to convention centers. What the companies get in return is well shrouded, but company logos on official society slides and publications reflect a minimal visible evidence of sponsorship. Especially problematic at these meetings are company-sponsored talks by company-paid speakers. Some are held only outside of the official program (but still approved by the society) and in other meetings are blatantly interspersed in the official scientific program. Once again, the drug companies are not only to blame. Many medical societies solicit drug company support with flagrant come-ons that tout the benefits to the companies of reaching their elite professional members.

Any consideration of loosening the ties between the profession and industry must take into account the extent of the involvement. While we have little definitive information on the pervasiveness of these arrangements, we have hints that they are widespread. Medical journal editors complain that they are unable to find non-conflicted experts to serve on their editorial boards or to write editorials and review articles; financial connections of study authors listed in journal articles disclose as many as 10–15 companies for a single author. And the statement by the Washington Legal Foundation, an organization devoted in part to protecting the pharmaceutical industry from excessive regulation by the FDA and the ACCME issued the following statement, "It is widely acknowledged that most of the top medical authorities in this country, and virtually all of the top speakers on medical topics, are employed in some capacity by one or more of the country's pharmaceutical companies." If we take this statement at face value, which would certainly be appropriate given the close relationship of this organization to the drug industry, it suggests that industry has successfully co-opted an exceptionally high fraction of the most authoritative and influential members of the profession.

And what have leaders of the profession done to counter a trend in which the profession has become increasingly beholden to industry, at times to the detriment of the public that they have pledged to serve? Not much. Most professional organizations, including the American Medical Association and the American College of Physicians have published ethical guidelines but they allow physicians to receive gifts and meals and are silent on the appropriateness of membership on speaker's bureaus. Most have no proscription against members' involvement as consultants to industry for marketing or for the development of educational materials. Most professional organizations have no rules about what constitutes an ethical lapse, how they monitor their members' conflicts, or how they deal with a member who violates an ethical precept.

I do not underestimate the achievements of the pharmaceutical, biotechnology, and device industries. Neither do I want to stop the highly effective collaborations between academic scientists and these companies. In my recent book, I made this comment, "Thousands of physicians effectively collaborate with the pharmaceutical, biotechnology, and device industries to develop new diagnostic tools, prostheses, and medications. . . . I am not opposed to big business, to capitalism, or to making money. Viewed from a long-term perspective, these industries have produced medications that have extended life, prevented serious illnesses, and improved the quality of life of millions of people. The companies are also a vigorous engine that accounts, in part, for our country's phenomenal economic growth. Even if we were unwilling to overlook some of the inappropriate behavior of drug, device, and biotechnology companies, we would have to conclude that overall, the companies have produced a great many products that benefit us."

This brief description covers only a small fraction of the consequence of medical-industry financial connections. Flaws in research study design, bias in reporting of research, and risk to patients in clinical trials constitute other serious consequences, and a constant promotion of expensive drugs through free samples adds to the cost of care. I hope it is clear that the concerns I raised at the outset are real, namely that the medical profession has become excessively dependent on the largesse of the pharmaceutical industry, that these financial connections have a negative influence on the quality and cost of patient care and the trust of the public, and that the profession's response to these threats has been weak. By making tenacious financial connections with physicians, industry has tainted the very profession that it relies on to appropriately use its products, and, if anything, the companies are trying to tighten and extend the connections, increasingly recruiting physicians to their marketing efforts.

During the height of managed care, the public became aware of the influence of payment incentives on the kind of care they were receiving. They began to appreciate that they might be subjected to excessive testing when physicians were paid on a fee-for-service basis and denied testing when physicians were working in a capitated system. Survey studies show that the public is wary of physician involvement with industry, but nothing is a better guide to public awareness of physician-industry connections than the media. Already, episodes of inappropriate behavior by financially conflicted physicians have appeared in the comics in Dilbert and other cartoons and on television on ER and the Simpsons. Already there seems to have been a public devaluation of medicine: instead of medical experts arguing scientific issues in the public domain, the press now publishes debates about psychiatry between prominent Hollywood film actors, and commentaries about the toxicity of vaccines and the cause of autism by environmental lawyers.

I believe that the public will become increasingly exercised about the profession's tilt to industry. Given the extensive involvement, extracting medicine from industry's financial magnet will be extremely difficult, but I believe it must be done. Needless to say, Congress has the clout to set new rules, yet I continue to favor vigorous action by the profession. Such action will be painful, but probably less painful than inappropriate and more costly medical care or the opprobrium of a disenchanted public. I believe that if the profession fails to act, Congress should.

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Chairman JOHNSON OF CONNECTICUT. Thank you very much. Dr. Kassirer, your testimony is very interesting. It is very relevant to a consideration of how the FDA functions, and the responsibility of government to follow the experience of an approved drug. That experience, once it is population-wide is going to be very different than the experience in a clinical trial no matter how good that clinical trial. It is not directly relevant to how we implement pay for performance, except that as we get better and better at looking at quality of care, and what physician services support quality now, remember quality is going to be based on specialty groups, protocols, expert's opinion about what works and what

should be done when, and if you do it at this point, what will be the outcome.

As we are able to hold the system more and more accountable for those kinds of early actions, and as we ourselves are able to gather the information and pay more attention to what is the outcome, we will have a better and better physician payment system, and I think that it will affect our use of drugs. One of the problems is that we approve drugs on the basis of rather narrow clinical trials, and then we use them more broadly and sometimes, as you know, their off-label use turns out to be more important than the uses for which they were approved.

So, I appreciate the problem of drugs and the costs of producing new drugs in today's level of science, and I think all of those things are important. In our instance, ironically every time a doctor recommends a part B drug, he is, in a sense, sealing his own reduction in payment for the office visit. We count drugs under this global amount. It cuts his cost. As drugs get to be \$1,000, \$2,000 average use many years, in the 60-, 70,000—it actually works against him. We do not want that disincentive anymore than we want the incentive that you point to as a real danger of overutilization or inappropriate utilization of a drug.

So, I would also remind you that this is the Subcommittee that proposed, in the Medicare Modernization Act, that we go to electronic prescribing in 2 years, because that gets rid of—that looks at drug interactions, it looks at appropriateness, and it has some potential to weed out overuse and to reform the way we actually think about the treatment regimens that we are recommending. So, I do you thank you for your very knowledgeable statement. As to both of the other witnesses from the AMA and the American College of Surgeons, first of all, thank you for your collaboration and your discussion with us over many months, and with the Administration, and with the other specialty groups, because we could not have gotten to where we are without your input. We cannot go forward unless we continue to think and evaluate the process that has been developed so far.

I want to be sure that we are as serious about it as we need to be. I thought, Dr. Hedberg, your comments about the lack of family practitioners and the unwillingness of young students to go into these areas, absolutely true. Unless we can reward quality practice at that level, they will not come in, and the current system disadvantages them; because the more tests they run, the more they look at prevention, the more they have you come back to be sure that you are sticking to the regimen, the more likely they are to suffer a payment cut. So, it is a perfect example of how desperately we need to turn things around. Now, let me just make a last comment, and then I will give Pete a chance to ask questions and I will come back later.

This issue of team, of the new payment model that rewards team-based care. We had direct experience with that in reforming the oncology payment system. The reason we had to change the practice expense so much is that delivering oncology care as a team issue, the doctor is not there all of the time. The doctor is essential to it, but it is the doctor and his whole team that delivers it. When you look at prevention, particularly in some of the more com-

plicated diseases and complex cases, it is a team effort. It is you, your nurse, you may even have to hire someone who does nothing but oversees and manages and provides the management component that we know is useful to good care. We just passed a bill we were all proud of, \$25 million for care managers just in cancer, because we know it is hard to manage, to navigate the system; because it is not just about the treatment, it is getting exercise, it is right diet, it is all of those things, and compliance means better health and lower health care costs.

So, we do not, in the proposal that we will make available to circulate now—we are waiting until after this hearing—you will see, we do not get there, but we do allude to it. I do not know yet how to look at team medicine in anything other than the narrow world of oncology care delivery, but you are absolutely right, and I want to work with you. I do not want to jump into bundled payments; that can be a nightmare. So, thank you for bringing it up and for acknowledging its importance.

For those of you who have been so helpful in us making this first step, it is only a first step, but if we can repeal the SGR and put in place something—a fair payment system that gives us the power that Pete is very concerned with, to control volume growth, I am convinced we can reduce the rate of growth in part B premiums, by better analyzing and having better opportunity to look at every one of the factors, sort of encompassed under the SGR, and properly managing their growth. So, let me turn to Pete now and see what he has.

Mr. STARK. Well, we have heard of a lot of testimony about paying doctors and not very much about helping patients, which I guess is a concern of many of us. Dr. Armstrong, representing an agency or a group, AMA, whose membership has been declining for the past 5 years, you now represent less than a quarter of the doctors in the country, it used to be two-thirds, somebody had suggested, Dr. Wolf, that you have not been doing a very good job. Your statement that you staunchly are committed is wonderful. I do not know who wrote that for you, but, as somebody said, you follow the money. I think that was the guy from the Federal Bureau of Investigation, Deep Throat, who said follow the money.

Well, \$5 million over 5 years. Once you spent \$600,000 trying to defeat me and Andy Jacobs and we got higher percentages that year than we ever did. I am so proud of you; \$5 million or \$1 million a year for quality. In the same 5 years, you spent \$65 million on lobbying firms. So, that shows you; \$65 million to mostly lobby us to pay you more, and \$5 million on quality. This last June though, you just broke the bank, and I think this is spectacular. A \$60 million program—this is \$60 million a year that you are going to start to improve your image and portray doctors as everyday heroes. Now, I think that is what this country needs. I hope those television shows of you doctors driving around in those Porsche convertibles with your lances out there going after the dragons—I just think \$60 million a year, that is \$300 million, \$65 million on lobbyists, that is \$365 million, and all of the time you are spending \$1 million a year on quality.

I think for the AMA and its members, that says it all. So, now we go to this question, and through all of the testimony, Dr.

Hedberg, yours, Dr. Armstrong, everybody says, you got to reward us, you cannot penalize us. You do not want us to tell anybody who does not live up to the standard, you want more money, and you resist in here the fact that we might cut the pay for doctors who are lousy performers. Now, Dr. Kassirer, have you seen the working draft of the recommended starter sets of clinical performance measurements for ambulatory care?

Dr. KASSIRER. No.

Mr. STARK. Let me go through a few of these just real quickly: breast cancer screening, colorectal cancer screening, cervical cancer screening, tobacco use, advising smokers to quit, inoculations for few vaccinations, pneumonia vaccinations, drug therapy for lowering cholesterol, and I go on and on and on, diabetes management. Have you ever seen, or do you know of any medical school, including that famous school in Grenada, that could graduate as a medical doctor who would not know this as rote hornbook medical care? Is there anything in there that the rawest recruit out of medical school would not know even before they did their internships?

Dr. KASSIRER. Well, Mr. Stark, these are really very common indices of health outcomes.

Mr. STARK. Pretty standard, are they not?

Dr. KASSIRER. I would say so.

Mr. STARK. Would you say that any graduate of any medical would not know about this stuff?

Dr. KASSIRER. I would not go quite that far, Mr. Stark, but at Tufts, it is certainly something that everybody should know.

Mr. STARK. All right. Now, why in God's name we should pay extra to people for doing what they know they ought to do—and, in fact, I think somewhere they took an oath that they would, and I hope in California that they had to pass a licensure test that says that they can understand this. On the other hand, what about saying we will raise everybody's pay? That is what the two gentlemen to your right are here for; they do not care much about patients, they care about getting more money.

Dr. KASSIRER. Oh, I doubt that.

Mr. STARK. Come on. If we raised their pay, what about saying we raise everybody's pay, but anybody who does not adhere to these things gets dropped from the program, or penalized or sent to jail, I do not care what. In other words, what is wrong with turning it around and saying, okay, we will pay you more, but we penalize people who do not perform.

Dr. KASSIRER. Well, Mr. Stark, I think this is a fundamental question about what is an important financial incentive to physicians. The answer is, that there are all kinds of financial incentives, and what you would like to do is put the incentives in the right place. Coming back to your comment, Madam Chairman, I would say the same thing. The question is, where are the incentives? Are in they in the right place or the wrong place? With respect to some of the Medicare reimbursements, they are clearly in the wrong place. As I mentioned in my testimony, and as Dr. McClellan mentioned before, with respect to cancer care, they are in the wrong place. With respect to Natrecor, they are in the wrong place. That is the sort of thing that needs to be fixed.

Chairman JOHNSON OF CONNECTICUT. Right. Thank you. Mr. Hulshof.

Mr. HULSHOF. Thank you, Madam Chair. Mr. Stark has made some interesting comments. Let me ask just, first of all, Dr. Armstrong, do you care about patients?

Dr. ARMSTRONG. Personally, and on behalf of the AMA and our 246,000 members, we care about patients first and foremost.

Mr. HULSHOF. Dr. Hedberg, I have got to ask you the same question. Do you, sir, actually care for patients?

Dr. HEDBERG. I was born into the family of an internist, and have spent all of my life hearing about and caring about patients. That is the most important thing in the world to me.

Mr. HULSHOF. Let us really then get to the crux, and I referenced this with Dr. McClellan, and it was more of—it was not specific, but, certainly, as the subject of this hearing is the SGR formula, and under the current Medicare system encouraging beneficiaries to utilize more physician services, and yet at the same time attempting to control the volume of physician services. Let me pick up on the thread that the gentleman from California has raised, and Dr. Hedberg, let us go to you, because the American College of Physicians has been one of the founding members with the Ambulatory Care Quality Alliance. What say you then about this challenge, if you will, that you know any resident knows that this 26-measure starter set, that this is a no-brainer? What do you say to that?

Dr. HEDBERG. Well, I would say this: it is hard to believe, but the figures that are taken out of practices and have been used in the “Crossing the Quality Chasm” report from the Institute of Medicine (IOM) show the chasm of quality. The figures that have been done in the ambulatory care areas where some medications, some on this list are used, show that they are used less than 50 percent of the time than they should be. We have a whole spectrum of doctors out there; we have older doctors, middle-aged doctors, younger doctors. I would think that, in this day and age, they would all know these things, but, when you go and look, you become amazed at what is going on, and I think we need quality improvement.

I would like to comment, too, at some point on what Chairman Johnson said about the change in the practice of medicine for chronic care, how that is changing and how prevention is becoming so important. This data, these first 26 performance measurements actually speak to the long-range care of patients, which goes beyond next year’s budget. The diabetic is prevented from blindness, heart attacks, renal failure, neuropathies in the legs, and much more, by the care that is done on a week-to-week, month-to-month basis in the doctor’s office. We don’t necessarily know about this, if we don’t have quality improvement data through using electronic health records, which are expensive to purchase for our offices. The money that Mr. Stark was talking about that I crave, as he alluded to, is really so that we can get these electronic health records and machines and computers into our offices, because, how do we know if we are doing poorly unless we can measure it? That is the revolution in medicine; we have to measure these things to know if we are doing it right. The figures show we have got a long way to go.

Mr. HULSHOF. Well, let me amplify something you said, because speaking of common sense and what we would expect the most basic general practitioner or resident to know, folks back home, going back to my first term of Congress on this Committee back in the Balanced Budget Act 1997—I know it is a four-letter word to many that are here in the room—but nonetheless, it took an act of Congress for us to actually focus on preventive screenings, early screenings for colorectal cancer, pap smears, Type II diabetes, test strips, mammograms in problem cases; it actually took an act of Congress for us to come up with these commonsense ideas to focus not just on the fiscal health of Medicare, but more importantly, the personal health of the beneficiary. So, I appreciate you responding to that. Madam Chair, thanks for letting me go out of order, given the other matters I have got going on.

Dr. HEDBERG. Thanks for the opportunity because this is germane to the whole picture

Chairman JOHNSON OF CONNECTICUT. Absolutely, very germane. Mr. Lewis.

Mr. LEWIS. Thank you very much, Madam Chair.

Dr. Kassirer, you asserted in your book and in your testimony today that there is much waste in the system because of this maybe unholy alliance between pharmaceuticals and physicians. As Members of Congress, we watch television, we listen to the radio, we read the newspaper, we see the weekly magazines, we see all of these commercials, we see all of these ads. I thought for a long time, when a patient went in to confer with a physician, they would say, Doctor, I saw this, I saw that, why don't you try this, give me this prescription. You are telling us that it is not really geared toward the consumer so much, but it is geared toward reaching the medical community, the physicians?

Dr. KASSIRER. Well, Mr. Lewis, direct consumer advertising is only a modest fraction of the total budget of advertising of the pharmaceutical, device and biotechnology industry. They spend about \$4.5 billion on direct consumer advertising. When you are sitting in your living room listening to why you should be taking Cialis or Viagra, what you don't appreciate is the overwhelming fraction of the \$20 billion or more that is spent by the pharmaceutical and device industries is going to doctors to influence doctors to make one decision or another. I think it is quite clear that the public is beginning to appreciate the problems with the connection between physicians and industry. We have already seen cartoons in Dilbert. We have seen other cartoons. We have also seen television programs, like "ER" and "The Simpsons," where doctors collaborating with industry are shown doing some pretty nasty things. So, the public is getting fed up with these complex relations between doctors and industry. If the profession doesn't do something about it soon, it is going to seriously harm the relationship between doctors and patients.

Mr. STARK. Would the gentleman yield for just a second?

Mr. LEWIS. I yield.

Mr. STARK. In an attempt to keep the AMA from portraying me as the antihero in these ads, I want to commend them because, as I understand, one of the principles that they put forth at their re-

cent convention was to restrict or limit these direct consumer ads for prescriptions, and they are to be commended for that position.

Mr. LEWIS. Dr. Kassirer, how will you go back correcting this? What will you recommend? Should there be action on the part of this Committee, on the part of the Congress?

Dr. KASSIRER. I would prefer that Congress stay out of it for now, quite frankly, yes.

Mr. LEWIS. I am not a physician, not a person of medicine like Dr. Stark—

Dr. KASSIRER. Well, I can make you a doctor very easily just by calling you it. I believe the profession needs to do something about it. I think bringing the attention of the public to it more, as I tried to do in my book, and talking about it more, getting much more widespread disclosure of how frequent these relationships are, how serious they are, is something that needs to be done first before, I hope, Congress does anything.

Mr. LEWIS. Thank you. Thank you, Madam Chair. I yield back.

Chairman JOHNSON OF CONNECTICUT. Thank you very much. Dr. Hedberg, you talk about the quality standards that you have developed. What would be the impact of those quality standards on office services?

Dr. HEDBERG. Well, I think two things. First, by knowing what your personal profile is on these things, we know that if doctors are given performance measurements results, compared with the rest of the country, that they will get better. Most doctors want to be good. They want to do their best, as Dr. McClellan said. It is hard to improve unless you have the data. Once you show that, of the hundred diabetics I have, too many of them have a hemoglobin A-1C, which is a blood-sugar measurement over a period of time, over the value of nine, that is not good. There is a certain desirable percentage. There are tough cases, and there are easy cases to do this with, and you should be able to tell from your own figures how you are doing. If you have a hundred patients with diabetes, you don't know until you collect the data. You will improve; your quality will improve. Furthermore, you will save, not only now but into the future, a lot of money because the patients won't come back needing amputations, needing retinal surgeries, needing cardiac bypasses. It is a very simple concept, but it stretches out over years, and the savings are going to be enormous.

I heard recently that just by putting in health information technology and totally connecting interoperable communications between doctors, which are very deficient in our country, and the communications between doctors, laboratories and hospitals we will probably save over \$100 billion a year. So, the savings are there.

Chairman JOHNSON OF CONNECTICUT. Well, I couldn't agree with you more that the savings in the electronic potential—concerning a solid electronic interoperable system is going to save us lots of money, eliminate errors, improve the quality for patients. In the 26 measures starter set, for instance, some of those measures are screenings for cancer, flu and pneumonia vaccines, diabetes patients' blood levels, cholesterol levels; now, those are all things that go on in the doctor's office. If we do all that, it is true we will save the system care, but under the current system, the doctor's payments will be cut. Now this hearing—

Dr. HEDBERG. Well, doctors don't share in those savings; that is for sure.

Chairman JOHNSON OF CONNECTICUT. That is the irony. Well, if we get good practice under the current law, we get poor payments. So, my colleague from California said, I haven't heard much about payments in this hearing—speaking about patients in this hearing but only about doc payments—this is all about patients, because if you deliver the care you need to deliver, you are going to improve the quality of health care and save them a lot of suffering and us a lot of cost.

On the other hand, under the current system, ironically, if you deliver that care, then we will have 10 years of 5 percent cuts rather than 7 years of 5 percent cuts. That is really a very, very big problem, because in the past years, reimbursement rates have gone up either not at all or very well below inflation. We know what happens when that happens because we have done it in Medicaid. It is not as if this country doesn't know what happens when you don't pay people for the work they provide; they stop participating in your system. So, in many parts of the country, it is very hard for patients to find a doctor who will care for them under Medicaid.

One of the reasons I have introduced legislation and am determined to introduce legislation, in spite of the barriers of the supposed make-believe costs, to repeal one system and replace it with another that I think will be more accountable on the issues of quality and volume, is because if we don't do it, it isn't rocket science what will happen. It is predictable. It is simple, and it is inevitable. Reimbursements will fall, and professionals will either not join the specialties we need, or not join the programs we want. Now, if any one of you disagrees with that, you better tell me, but then I have one other question I want to ask. So, anyone disagree with that?

Then the last thing I want to ask you is, the IOM's studies, which were really the incentive for all of this—the quality chasm incentive, and what it told you was something we have known a long time. We just didn't do anything about it. You can make this analogy in public education. I first heard this as a freshman Member of Congress in the eighties, that it took 15 years from the time we thought up a new weapon system to the time we decided to do it. We produced it. We trained. We integrated it into frontline. That is unacceptable. That is what the IOM study said, too. It is 15 years from the time we invented a new treatment to the time we got compliance out there. In today's world, that is simply unacceptable. The rate at which new diagnostic capabilities are developing, new treatment capabilities, new pharmaceutical options, we can't do it that way anymore.

So, I think the importance of what all of you have said is that we have to move to a new system, and we have to back it with the educational and technological components to make it work. The drugs, you have to provide help for the physicians to understand how some of these new very complicated and different types of drugs are going to work and what to watch for. How we do that, whether the old system, pharmaceutical agents visiting—certainly the old system of annual meetings isn't going to work; it is not equal to the task. Advertising at least lets consumers know that you might want to ask about this, but it is driving inappropriate

care. So, we have a big job cut out for us if we are going to create a system in which we deliver the right care at the right time to get the maximum quality of life for people who either have short-term or long-term illnesses.

So, it is a huge challenge. I look forward to your input as we go through the process of developing this bill. When anything starts out like this in the House and the Senate, it has a long road to travel, and I invite you all to participate. I would mention to you, Dr. Kassirer, you probably aren't aware of this—I wasn't aware of this—but the direct to consumer voluntary guiding principles have received preliminary approval from the board, so your book has apparently hit home. I will be interested in your feedback on that issue. Thank you for being with us at this time.

Mr. STARK. I would like to ask the panel this—

Dr. KASSIRER. Excuse me, Mr. Stark. Could I be excused? I have to leave—

Chairman JOHNSON OF CONNECTICUT. You certainly can. Thank you for being here and for your testimony.

Mr. STARK. I would ask the remaining panelists this: There has to be an incentive, I presume, in the fees. I have contended that, with the cuts we are talking about, physician income hasn't dropped that much, totally. Per procedure fee has dropped, but the gross payments have either gone up or remained the same. In my district, half the people, not half the insured, but half the people in my district, somewhere over 300,000, receive their medical care from physicians who are paid on a salary. What do I do with them? Can I not, if I were running—half my constituents are in Kaiser Permanente, so do I just say, Doc, your salary gets cut if you don't live up to this? Or what do we do there?

Dr. HEDBERG. Who are you asking?

Mr. STARK. Either of you.

Dr. HEDBERG. Well, I spent half my career in private practice and half of it being in a university, so I have been under both systems. The pressure in the university system—and that is a salaried doctor you are talking about—is that the payments are the same as in private practice. If you are coding, you send in your charges; your secretaries take care of it, but you get the same amount. The dean of the medical school can then say your costs are too high. So, you have a middle man, but you are still responsible to be fiscally sound in most salaried positions. You are still responsible for productivity.

So, I think you just go ahead with the total package, and the middle man has to deal with it back at the university, and you still have to deal with it to be productive for the people you are working for. I haven't found too much difference hanging by my fingernails to keep my private office practice going, or hanging by my fingernails to see enough patients to keep my salary going. I think that is the way it is working now, and I think it is pretty much the same for private practice and salaried physicians. By the way, when you are in a system that is as good as Kaiser Permanente, you have a lot of quality performance help, too.

Mr. STARK. Yes, we do, but I would presume that they would lay this tablet down before their physician group and say—

Dr. HEDBERG. Oh, they do.

Mr. STARK. Ladies and gentlemen, these are our procedures, and if salaries are adjusted, that would be something else again.

Dr. HEDBERG. It is very common now, in salaried positions, to adjust them for the amount of patients you see.

Mr. STARK. Also for your productivity.

Dr. HEDBERG. Exactly.

Dr. ARMSTRONG. Regardless of the practice setting, there needs to be viable practice economics.

Mr. STARK. Then it could be an increase in the overall payment with a penalty for not performing really; could it not? The physicians could come out pretty much the same way. You are suggesting, I believe, both of you, that we shouldn't penalize the physician who doesn't voluntarily prescribe to these new benefits. I am saying, why not say all physicians have to do this, and we will raise the pay?

Dr. HEDBERG. You mean like performance measurements—

Mr. STARK. As in, if you don't do it, we will then penalize you.

Dr. HEDBERG. Well, sure. All of us now have to do performance measurements within our employment.

Mr. STARK. Like I said, it could have worked either way. I'm not sure Armstrong would agree.

Dr. ARMSTRONG. I don't think we do well when we penalize. I think we do much better to provide a viable practice economics as a framework upon which to build system-wide quality improvement efforts, and incentives go a long way toward doing that. We have to remember that quality improvement is a system-based effort. We have to think of everybody involved in the care of patients and focus on those linkages across the system.

Chairman JOHNSON OF CONNECTICUT. Would the gentleman yield?

Mr. STARK. I thank the Chair.

Chairman JOHNSON OF CONNECTICUT. In the hospital arena, we provide a full market basket if you meet all the criteria, and less than that if you don't. That is the model that is in my proposed bill, full Medicare Economic Index (MEI) if you meet all the criteria; MEI minus 0.5 if you don't. Now, that is not a lot of penalty, but it should be enough to get people's attention. I think that that is easier than the other way, which given our budget constraints would be everybody gets MEI minus 0.5, and then if you achieve it, you get MEI, which is really the same thing. So, I don't want it to be seen as punitive, but there does need to be a differential between one or the other. Now, the last question I forgot to ask you was profiling. You both have had experience in profiling. The Administration intends to profile according to claims data. Insurance companies frequently do this. Others have said to me, it is not adequate, claims data. What do you each think about that? What do we need to profile effectively and honestly?

Dr. ARMSTRONG. You need the right data, and you need data that reflects accountability for the care that has been provided, data that can be easily collected, data that is evidence-based.

Chairman JOHNSON OF CONNECTICUT. Presumably, we will have that, if we set these measures correctly, because we are conscious, and we would say in the law that they have to be evidence-

based and they have to be easily collected. So, is that going to be adequate?

Dr. ARMSTRONG. That is a step in the right direction, but the larger issue, after one gets the data, is how one actually reports this data. We want to make sure that, in the process of reporting data, particularly on individuals, understanding that quality of care is a system issue, we want to be very careful that we do not create disincentives to care for the sickest patients, the most vulnerable patients in our society.

Chairman JOHNSON OF CONNECTICUT. For the least compliant, for one reason or another.

Dr. HEDBERG. I was going to say a risk adjustment is extremely important here because you have disparities in care that comes from different socioeconomic populations. You don't want to have doctors who are taking care of people who are disadvantaged or are noncompliant penalized because patients can't afford to get to the doctor for one reason or another. We have courageous physicians who spend all their time on that, and their profiling may not look too good because the patients aren't as compliant and, for very good reasons having to do with their socioeconomic environment, can't participate in their own care.

Particularly people in poverty. We know they don't do well. If the doctor's lab data is looked at for not having done this and that and they haven't come in, well, he can be seen as a poor physician, and I think that is not fair. So, I think doctors are very cognizant of this, and they want to be sure when this profiling is done, that it is adjusted for that. We don't have good risk adjustments now, particularly in primary care. It might be a little easier to do in surgery, but we don't have them in primary care. We have to work on that.

Chairman JOHNSON OF CONNECTICUT. Well, it might be useful if you would give us something in writing on this subject because this is the most difficult subject.

Dr. HEDBERG. It is really.

[The information was not received at the time of printing.]

Chairman JOHNSON OF CONNECTICUT. While we do recognize it all in our draft, over time, we do need to kind of—

Dr. HEDBERG. Actually, the scheme that you are working on and what we have been very interested in, as this process unfolds over the next 3 to 4 years and fully comes in—the full pay-for-performance in the year 2009 gives us time to work on adjustment like this that are really important.

Chairman JOHNSON OF CONNECTICUT. We may want to specify certain things that need to be focused on during that time period because some of these issues are very, very hard, and we just don't know. So—

Dr. HEDBERG. I'm appreciable to your appreciation of that.

Chairman JOHNSON OF CONNECTICUT. That would be an improvement, thank you. Thank you all. The hearing is concluded, and I thank the Members who stayed.

[Whereupon, at 3:28 p.m., the hearing was adjourned.]

[Submissions for the record follow:]

Statement of Jack Ebeler, Alliance of Community Health Plans

The Alliance of Community Health Plans (ACHP) commends the Ways and Means Health Subcommittee for convening a hearing on the opportunities for Medicare to use value-based purchasing of physician services to improve quality. We are pleased to have the opportunity to share our perspective.

ACHP is a leadership organization of non-profit and provider-sponsored health plans that are among America's best at delivering affordable, high-quality coverage and care to their communities. Today, ACHP member plans serve more than one million Medicare beneficiaries—about 20 percent of current Medicare Advantage members.

ACHP has a proud legacy of leadership on quality improvement and was formed more than twenty years ago to help innovative health plans share best practices. One of the earliest products of this collaboration was the creation of the Health Plan Employer Data and Information Set (HEDIS®), which has now become the standard for assessing health plan performance in the commercial and public sector. Through the National Committee for Quality Assurance (NCQA)—which today manages and updates the HEDIS® measurement process—employers, Medicare, Medicaid and other payers regularly monitor and evaluate health plan quality.

Health plan measures assess plans' performance in areas such as cancer and heart disease screening and prevention, control of diabetes risk factors, and how well patients feel the plan and their physician listen to them. To help Medicare beneficiaries make informed decisions about their health plan choices, CMS makes comparative information about plan performance available on-line through www.medicare.gov and in printed publications. Together, the HEDIS® clinical quality reporting process, coupled with the CAHPS® survey of patient satisfaction, provide a vital and meaningful assessment of health plan performance for beneficiaries and for public and private payers.

Quality Matters

A 2003 comprehensive, peer-reviewed RAND Health assessment of health care quality published in the *New England Journal of Medicine* found that Americans received recommended health care only about half of the time. NCQA's 2004 *State of Health Care Quality* report documented that the gap between the quality of care delivered through the nation's best health plans and the care most Americans receive results in an estimated 42,000 to 79,000 premature deaths each year. Yet, as the Medicare Payment Advisory Commission (MedPAC) has said, the Medicare program is largely neutral or negative towards health care quality. Medicare providers are paid the same regardless of the quality of service provided and, at times, are paid more when quality is worse.

To address the quality chasm in health care, the Institute of Medicine (IOM) has called for realigning financial incentives to achieve better patient outcomes. MedPAC also has recommended the introduction of quality incentive payment policies in Medicare for health plans, physicians, hospitals, dialysis facilities and home health agencies.

Having led the way in establishing health plan performance measures, ACHP echoes the IOM and MedPAC's assessment that pay-for-performance is an idea whose time has come. We share the Subcommittee's commitment to advancing the use of quality measures in fee-for-service Medicare. For beneficiaries to make well-informed health care choices, they need to be able to make "apples-to-apples" comparisons between the quality of care in Medicare Advantage plans—which they can evaluate through publicly reported data on a range of quality measures—and the care offered by fee-for-service Medicare providers—for which public reporting is just beginning. Today's hearing is an important step in advancing this goal.

Next Steps

Mark McClellan, M.D., Ph.D., Administrator of the Centers for Medicare and Medicaid Services (CMS), indicated in his June letter to Ways and Means Committee Chairman Bill Thomas that CMS has been working with physician groups and other stakeholders on the development and use of quality measures for physician-related services. Many of the measures under consideration are drawn from the HEDIS® measure set that has been developed and refined through health plan use. We are pleased that the lessons learned from health plans' experiences with quality measurement are helping to inform the evolution of physician measurement. We look forward to serving as a resource to the Subcommittee as it continues its work on this issue.

In addition, as the Subcommittee moves forward in its consideration of value-based purchasing for physicians, we encourage you to consider the opportunities offered by introducing value-based purchasing in Medicare Advantage. Having spent

considerable time examining how Medicare could help beneficiaries receive higher quality health care, MedPAC's June 2003 assessment of where and how to begin pay-for-performance in Medicare pointed to health plans as a likely starting point. MedPAC noted that Medicare Advantage plans are good candidates for quality incentives because "they meet, in whole or part, all of the criteria for successful implementation." Medicare Advantage plans have:

- Standardized, credible measures of performance and customer satisfaction that are reported annually to CMS;
- Data collection capacity and mechanisms to report on quality measures already in place;
- Leverage to improve performance across the variety of settings with which they contract; and
- Opportunities to improve coordination of care across settings in a way that is "not possible through provider-specific efforts."

ACHP and Pay-for-Performance

ACHP believes that adopting pay-for-performance for Medicare Advantage plans would be an important initial step in moving Medicare toward a more performance-driven system, while also helping to advance the development of measures and mechanisms for using incentives with physicians, hospitals and the other health care sectors.

ACHP's work on value-based purchasing is informed by our key principles for pay-for-performance. They include the following:

- Payment-for-performance incentives should eventually apply to all Medicare providers, including fee-for-service and Medicare Advantage. Given health plans long record of reporting on standardized measures of quality, it is reasonable to begin with Medicare Advantage plans, including HMOs and PPOs.
- Pay-for-performance incentives should be based upon standards of excellence and improvement.
- Measures to evaluate both fee-for-service Medicare and Medicare Advantage plans should be developed. In the interim, incentives should be based on existing measures and should emphasize clinical effectiveness.
- To ensure successful implementation and sustainability, pay-for-performance incentives should be financed with a new, dedicated stream of funding.

We share your strong commitment to ensuring that Medicare beneficiaries have access to quality information about all of their Medicare options and applaud the Subcommittee for its ongoing efforts to examine value-based purchasing models for physicians. We agree with MedPAC's assessment that health plans are a logical place to begin using quality payment incentives and that Medicare should aggressively work to develop quality measures for other sectors, including fee-for-service settings such as physician offices.

Thank you for the opportunity to share our views. We look forward to working with the Subcommittee on this and other issues of mutual interest.

Statement of Michael Fleming, American Academy of Family Physicians, Leawood, Kansas

Introduction

This statement is submitted on behalf of the 94,000 members of the American Academy of Family Physicians to the House Ways and Means Subcommittee on Health as part of its hearing on Medicare Physician Reimbursement Issues, scheduled for Thursday, July 20, 2005. The AAFP greatly appreciates the work that this subcommittee has undertaken to examine how Medicare pays for physician services and we share the subcommittee's concerns that the current system is unproductive. This is why the AAFP supports the restructuring of Medicare payments to reward quality and care coordination. This restructuring must be built on a fundamental reform of the underlying fee-for-service system.

AAFP currently has over 57,000 members in active practice, the vast majority of whom are in small and medium size practices, not large groups. We anticipate that this will be the typical construct of family medicine well into the future. Most people in this country receive the majority of their care from physicians in small and medium size ambulatory care settings. Currently about a quarter of all office visits in the U.S are to family physicians, and the average family practice has about a quarter of patients who are Medicare beneficiaries. Implementing value based pur-

chasing or pay for performance in the Medicare program has tremendous implications for millions of patients and for the specialty of family medicine, and AAFP is therefore committed to involvement in the design of a new pay-for-performance program that meets the needs of patients and physicians.

Physicians and Pay for Performance

The AAFP supports moving to pay for performance in the Medicare program with the goal of continuously improving care of patients. As we recently stated in a joint letter to Congress with our colleague organizations ACP, AAP and ACOG, “we believe that the medical profession has a professional and ethical responsibility to engage in activities to continuously improve the quality of care provided to patients—Our organizations accept this challenge.” We have committed to work toward transformation of medical practice, to strengthen the infrastructure of medical practice to support pay for performance, and to engage in development and validation of performance measures. While several specific issues remain that must be addressed in implementing pay for performance in Medicare, AAFP has a framework for a phased in approach for Medicare.

AAFP is involved in several efforts that are fundamental to moving toward a pay for performance system.

First of all, we know that the development of valid, evidence-based performance measures is imperative for a successful program to improve health quality. The AAFP participates actively in the development of performance measures through the Physician Consortium for Performance Improvement. We believe that multi-specialty collaboration in the development of evidence-based performance measures through the consortium has yielded and will continue to yield valid measures for quality improvement and ultimately pay for performance.

The AAFP was the first medical specialty society to join the National Quality Forum (NQF). And along with ACP, AHIP and AHRQ, the AAFP is a founding organization of the Ambulatory care Quality Alliance (AQA). However, it is important to distinguish between the role of the NQF and that of AQA. With its multi-stakeholder involvement and its explicit consensus process, the NQF provides essential credibility to the measures that it approves—measures developed by the Physician Consortium, NCQA and others. The AQA’s purpose is to determine which of the measures approved through the NQF consensus process should be implemented initially (the starter set), and which should then be added so that there is a complete set of measures, including those relating to efficiency, sub-specialty performance, and patient experience. Having a single set of measures that can be reported by a practice to different health plans with which the practice is contracted is critical to reducing the reporting costs borne by medical practices. Measures that ultimately are utilized in a Medicare pay-for-performance program should follow this path.

Information Technology in the Office Setting

Health information technology effectively utilized in the physician’s office is necessary to the success of quality improvement and pay-for-performance programs. We have learned from the Integrated Healthcare Association’s (IHA) experience in California that physicians and practices that invested in EHRs and other electronic tools to automate data reporting were both more efficient and achieved better quality results, and did so at a more rapid pace than those that lacked advanced HIT capacity. The AAFP created the Center for Health Information Technology (CHiT) in 2003 to facilitate adoption and optimal use of health information technology with the goal of improving the quality and safety of medical care and increasing the efficiency of medical practice. We now estimate that over 20 percent of family physicians are utilizing EHRs in their practices, which is twice the number from this time last year. Through a practice assessment tool on the CHiT website, physicians can assess their readiness for EHRs. We know from the HHS-supported EHR Pilot Project conducted by the AAFP that practices that had a well defined implementation plan and analysis of workflow and processes had greater success in implementing an EHR.

We also know that cost can be a barrier to IT adoption and have worked aggressively with the vendor community through our Partners for Patients Program to lower the price point. The AAFP’s Executive Vice President serves on the Certification Commission for Health Information Technology (CCHIT) which certifies EHRs. The AAFP sponsored the development of the Continuity of Care Record standard, now successfully balloted through the American Society for Testing and Materials (ASTM). We initiated the Physician EHR Coalition, now jointly chaired by ACP and AAFP, to engage a broad base of medical specialties to advance EHR adoption in small and medium size ambulatory care practices. Our Board of Directors has set an ambitious goal of having 50 percent of family physicians using EHRs

by the end of 2005. We are committing our organizational resources to assist our members achieve this goal.

The AAFP quality initiatives span efforts to emphasize measures like quality improvement, office redesign, and integration of the chronic care model. Here are two examples. Through our Practice Enhancement Program, teams of physicians and their office staff participate in an intense educational experience accompanied with pre and post course work to acquire the practical tools, skills and knowledge to implement the planned care model into their everyday practices. Through the web-based METRIC (Measuring, Evaluating and Translating Research into Care) program, family physicians assess their systems in practice, review charts and enter patient data, receive feedback on their performance, implement a quality improvement plan, re-measure and reassess. Two module topics currently are available: diabetes and coronary artery disease.

The AAFP takes seriously the responsibility to work with our members to continuously improve their clinical care and office infrastructure to better meet the needs of their patients.

Current Payment Environment

While these innovations are exciting and hold great promise, the environment in which physicians practice is challenging at best. And it will come as no surprise that family physicians, while they enjoy caring for their patients, are not enthusiastic about the Medicare program. This program has a history of disproportionately low payments to family physicians, largely because it is based on a reimbursement scheme that is designed to reward volume and to discourage innovations in the provision of care. In general, the prospect of annual cuts in payment is discouraging. The regulatory approach is punitive, and physicians live in fear of violating rules they don't even know about. In the current environment, physicians know that they will face a 4.3-percent cut in January 2006, and that without Congressional action to repeal the Sustainable Growth Rate formula and create a structure for sustainable financing, they face steadily declining payments into the foreseeable future, even while their practice costs are increasing. To overlay a pay-for-performance program in Medicare, therefore, poses a unique set of challenges and it must be done thoughtfully and carefully because of its size and complexity.

Our consistent message to Congress is that if it is not done well, a value-based purchasing program will not only fail to improve health care quality but could unravel the preparation and progress that medical specialty societies have carefully undertaken.

"Doing it well" means phasing in a value-based purchasing program that provides incentives for structural and system changes, that encourages reporting of data on performance measures and ultimately rewards continual improvements in clinical performance. Yet, moving the Medicare program in this direction cannot be accomplished in an environment of declining physician payment; Congress must take steps to stabilize physician payment through positive updates, as proposed by MedPAC. Furthermore, because of its financing structure with Part A and Part B, we believe it is important that Congress require a report on Medicare program savings resulting from Part B quality improvement efforts so that physicians are not penalized into the future.

A Framework for Pay for Performance

The following is a proposed framework for phasing in a Medicare pay-for-performance program for physicians that is designed to improve the quality and safety of medical care for patients and to increase the efficiency of medical practice.

Phase 1:

All physicians would receive a positive update in 2006, based on recommendations of MedPAC, reversing the projected 4.3-percent reduction. Congress should establish a floor for such updates in subsequent years.

Phase 2:

Following completion of development of reporting mechanisms and specifications, Medicare would encourage structural and system changes in practice, such as electronic health records and registries, through a "pay for reporting" incentive system such that physicians could improve their capacity to deliver quality care. The update floor would apply to all physicians.

Phase 3:

Assuming that physicians have the ability to do so, Medicare would encourage reporting of data on evidence-based performance measures that have been appropriately vetted through mechanisms such as the National Quality Forum and the

Ambulatory Care Quality Alliance. During this phase, physicians would receive “pay for reporting” incentives; these would be based on the reporting of data, not on the outcomes achieved. The update floor would apply to all physicians.

Phase 4:

Contingent on repeal of the SGR formula and development of a long term solution allowing for annual payment updates linked to inflation plus funds to provide incentives through pay for performance programs, Medicare would encourage continuous improvement in the quality of care through incentive payments to physicians for demonstrated improvements in outcomes and processes, using evidence-based measures such as the provision of preventive services, performing HbA1c screening and control, prescribing aspirin to diabetics, etc. The update floor would apply to all physicians.

This sort of phased-in approach is crucial for appropriate implementation. While there is general agreement that initial incentives should foster structural and system improvements in practice, decisions about such structural measures, their reporting, threshold for rewards, etc. remain to be determined. The issues surrounding collection and reporting of data on clinical measures are also complex. For example, do incentives accrue to the individual physician or to the entire practice, regardless of size? In a health care system where patients see multiple physicians, to which physician are improvements attributed?

The program must provide incentives—not punishment—to encourage continuous quality improvement. For example, physicians are being asked to bear the costs of acquiring and using health information technology in their offices, with benefits accruing across the health care system—to patients, payors, insurance plans, etc. Appropriate incentives must be explicitly integrated into a Medicare pay-for-performance program if we are to achieve the level of infrastructure at the medical practice to support collection and reporting of data.

The AAFP appreciates the opportunity to share our enthusiasm for, yet caution about, a Medicare pay-for-performance program.

American College of Obstetricians and Gynecologists
Washington, DC 20024
July 22, 2005

The Honorable Nancy Johnson
Chair, Health Subcommittee
Ways and Means Committee
1136 Longworth House Office Building
Washington, DC 20515

Dear Mrs. Johnson:

On behalf of the American College of Obstetricians and Gynecologists (ACOG), representing 49,000 physicians and partners in women's health, thank you for the extraordinary leadership and commitment you've shown in your effort to correct a serious problem in the Medicare program by repealing the flawed Sustainable Growth Rate (SGR) formula and putting in place a system that works for physicians, and helps ensure access to high-quality care for our patients.

ACOG has long been dedicated to maintaining the quality of care provided by obstetricians and gynecologists and has a robust ongoing process where we provide women's health physicians and providers with current, quality information on the practice of obstetrics and gynecology. For nearly two decades, ACOG's Committee on Quality Improvement and Patient Safety has regularly reviewed practice and patient safety issues and encouraged our members to incorporate ACOG's recommendations into their practices. ACOG's Practice Committees regularly publish practice guidelines developed by committees of experts and reviewed by leaders in our specialty and the College. Each of these guidelines is reviewed periodically and reaffirmed, updated, or withdrawn based on new clinical evidence to ensure continued appropriateness to practice.

In 2004, in cooperation with the American Board of Obstetrics and Gynecology (ABOG), an independent, non-profit organization that certifies obstetricians and gynecologists in the United States, ACOG created Road to Maintaining Excellence, an initiative to allow ob-gyns to evaluate their own practice activities, reinforce best practices and assist in improving others. Road to Maintaining Excellence requires ACOG Fellows to complete questionnaire-based modules that focus on a single aspect of clinical practice, like prevention of early-onset group B Streptococcal disease in newborns and prevention of deep vein thrombosis and pulmonary embolism. As

Fellows complete each module, data is summarized and compiled by ACOG, and periodically reported to our members.

ACOG has been working collaboratively with our primary care colleagues, as well as our colleagues in specialty and surgical care, to be supportive of moving toward value-based physician payments, linked with fixing the SGR. As Congress moves forward in establishing quality incentives in Medicare, ACOG believes that certain principles should be kept in mind, many of which are reflected in your discussions of pay-for-performance and your draft legislation.

- All physicians should receive a positive Medicare payment update as a floor for additional reporting or performance incentives. Under the current SGR formula, physicians will receive unsustainable payment cuts of nearly 30 percent over the next six years. Some performance measures may involve additional office visits, lab tests, imaging exams or other physician interventions that would only exacerbate the current volume formula. Physicians must not be penalized for any volume increase resulting from compliance with performance measures. To ensure an equitable accounting of the costs and savings generated from pay-for-performance, Medicare should account for savings to Part A generated by Part B performance improvements.
- The new payment system should be phased in, beginning with an administratively simple “pay-for-reporting” period that provides information about the quality and safety processes physicians are engaged in and assesses the availability of health information technology. Quality and safety process measures used in the Medicare system should have widespread acceptance in the medical community. One such process measure in obstetrics could involve use of a prenatal flowsheet, a performance tool developed by ACOG that was recommended for use by an ACOG-led prenatal workgroup of the American Medical Association’s Physician Consortium for Performance Improvement. In ob-gyn surgery, ACOG supports the procedural measures laid out in the first phase of the American College of Surgeons Framework for Surgical Care, including confirmation of operative site and side marking, pre-operative “time out,” immediate post-operative documentation, post-operative pain management and appropriate post-operative care.
- Clinical performance measures should be developed by each specialty in a transparent process that considers scientific evidence, expert opinion and administrative feasibility of each measure. Measures should be appropriately risk-adjusted to account for a variety of factors, including patient compliance and complexity. Increased quality should be the goal of efficiency measures, and these measures, too, should be driven by data-based clinical evidence and expert opinion when data are lacking.
- Health information technology is prohibitively expensive for some small practices, particularly for the 23 percent of ob-gyns in solo practice, but is a necessary efficiency and a vital component of pay-for-performance. Acquisition of this technology should be encouraged with federal financial assistance for the purchase of hardware and software and for system training. National standards for health information technology would facilitate physician adoption of these systems, by reassuring physicians that the technology they invest in would not become obsolete. Because use of health information technology may be among the elements of the early “pay-for-reporting” system, it is vital that these steps be taken promptly.
- Congress needs to address the universe of legal issues surrounding data reporting. Information collected by CMS must be protected from use in medical liability litigation against physicians or as a basis for negligent hiring or retention claims. This may necessitate specifically exempting physician data from Freedom of Information Act requests. Care should be taken to avoid other unintended and unfortunate consequences of public data reporting, such as physician selection of patients with the fewest medical risk factors or the best history of compliance with instructions. This is essential to ensure continued access to care for low-income and minority populations who tend to enter the health care system at an acute stage of disease and illness and suffer worse outcomes regardless of the quality of care they receive.

We recognize the challenges in creating a quality improvement program for Medicare that leads us to meaningful clinical measures and improved quality for beneficiaries. We applaud your leadership and your commitment to this effort and we sincerely thank you for your willingness to work cooperatively with ACOG and the

medical community in these important discussions. ACOG stands ready to work with you as we embark on this historic change in Medicare.

Sincerely,

Michael T. Mennuti, MD, FACOG
President

American College of Surgeons
Washington, DC 20007
July 20, 2005

The Honorable Nancy L. Johnson
Chair, Subcommittee on Health
Ways and Means Committee
U.S. House of Representatives
Washington, DC 20515

Dear Mrs. Johnson:

The undersigned surgical specialty organizations are grateful for your leadership in developing and promoting reforms to the Medicare physician payment system. In particular, we appreciate your efforts to balance calls for restructuring current physician payment incentives with the need to eliminate the sustainable growth rate system that has destabilized the program and now threatens the financial viability of physician practices and patient access to care.

As the Ways and Means Health Subcommittee continues to review these issues, especially the many practical concerns involved in developing a meaningful value-based purchasing program, it is important to keep in mind the diversity of physician practices and services. In particular, it seems that much of the discussion to-date has focused on ambulatory services such as chronic disease management and preventive care, with little acknowledgement of the very different concerns associated with acute care procedures or hospital-based care. Even within surgery, there are substantial differences between hospital and ambulatory services that must be taken into account. The implications and the strengths associated with such diversity must be assessed carefully if the changes that are being considered for the Medicare physician payment system are truly aimed at improving the quality and processes of patient care.

With that in mind, surgery offers the attached framework for consideration if Congress is to develop a broad-based quality improvement program for Medicare. Like your draft legislation, this framework envisions a phased approach that begins with broadly applicable and relevant measures that can be reported by physicians through administratively simple means. The starter set of five potential surgical measures addresses key patient safety goals and can be implemented promptly. Over time, more complex specialty—and service site-specific measures and systems—including but not limited to those described in the document—can be developed to ensure broad applicability and participation across specialties and across sites of service.

Thank you again for your leadership and your support. We all look forward to working with you further on developing effective Medicare payment system reforms.

American Academy of Ophthalmology
American Academy of Otolaryngology—Head and Neck Surgery
American Association of Neurological Surgeons
American Association of Orthopaedic Surgeons
American College of Surgeons
American Society of Cataract and Refractive Surgery
American Society of General Surgeons
American Society of Plastic Surgeons
American Urological Association
Congress of Neurological Surgeons
Society for Vascular Surgery
Society of American Gastrointestinal and Endoscopic Surgeons
Society of Gynecologic Oncologists
Society of Surgical Oncology
The Society of Thoracic Surgeons

DEVELOPING A QUALITY IMPROVEMENT FRAMEWORK FOR SURGICAL CARE

Surgical organizations have long stood for quality and safety. They were among the first to champion peer review reporting in morbidity and mortality conferences, and were at the forefront of developing standards for the facilities in which surgical care is provided. Although surgeons continue to advance evidence-based care, surgical specialists and the research and processes they have developed have largely been omitted from recent debates on ways to report and measure healthcare quality in a Medicare pay-for-performance program. Instead, the focus has been principally on public health and primary care services, and on processes that are relatively simple to measure through ambulatory service claims. If policymakers begin to pursue the development of pay-for-performance, surgical participation is vital.

It is important to highlight key distinctions in surgical quality improvement from preventive and chronic care quality measures. For example, surgery is more episodic and less focused on chronic disease management, preventive services, and screening. In surgery, the ultimate outcome produced by a specific intervention is much more immediate and clear than disease management strategies that may span many years. As a result, surgery lends itself much more readily to rigorous clinical outcome measurement. And, while it is typical for generalist physicians to see a wide array of patients, surgeons tend to have more focused areas of practice that make it difficult to apply broad quality measurement sets. Administrative records other than the operative report—such as claims records—provide much less useful information about processes of care because of the way surgery is packaged and billed. Finally, successful patient management in a primary care setting generally results in increased utilization of preventive services. In surgery, “more” rarely means “better” care. For surgery, the best measures focus on elaborate decision-making processes that call for direct action to determine the right procedures, at the right time, for the right patient. Surgical quality initiatives limit acute complications and provide immediate cost savings, with enhanced outcomes and improved operational efficiencies through process development.

Of course, individual physicians and specialties are in different stages of preparedness for participation in meaningful pay-for-performance programs. Some individuals do not have access to sophisticated information technology that facilitates participation, and some specialties have yet to develop the rigorous clinical evidence that is needed to identify processes of care that improve patient outcomes. Nonetheless, there is general consensus among leading surgical societies on an overall framework for any program intended to promote high-quality surgical care.

We envision a phased approach that will afford a process of continuous improvement in the overall quality of surgical patient care while allowing further progress on the development, testing, and refinement of new measures.

First Phase

Phase I would essentially implement a “pay for reporting” system focusing on administratively simple, self-reported information about processes that are widely accepted and promoted for their contribution to improving patient safety and advancing the principle of patient-centered care—which are among the aims included in the Institute of Medicine’s framework for improving the health care system, *Crossing the Quality Chasm*. In this phase, which can be implemented through claims-based reporting, we envision a set of standards that assures the surgeon’s role in improving quality and safety. These standards might include the following:

- **Confirmation of Operative Site and Side.** While rare, wrong-site or wrong-patient operations do occur. A wide range of physician organizations and specialty societies, along with other provider groups, payers, and accreditation organizations have not only called on surgeons but also on surgical team members and patients to ensure that the operative site is appropriately signed and confirmed by either the patient or a representative for the patient. So-called “sign your site” programs have been endorsed by the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO), Agency for Healthcare Research and Quality (AHRQ), Department of Veterans Affairs (VA), American Academy of Orthopaedic Surgeons, American College of Surgeons (ACS), and other national organizations representing surgical specialists and perioperative nurses.
- **Pre-Operative “Time-Out.”** When errors do occur in the operating room, poor communication among surgical team members is often cited as a key cause. In addition, after signing the site for surgery, a variety of circumstances, such as a change in scheduling or operating rooms, can occur and potentially lead to a wrong-site or wrong-patient procedure, or to an operation for which the surgical

team lacks the necessary tools or equipment. For these reasons, a broadly-endorsed technique known as the surgical “time-out”—a checklist type process based on airline safety practices—should occur prior to making the surgical incision. This process is currently endorsed and promoted by JCAHO, AHRQ, the VA, and a variety of national organizations representing members of the operating room team, including ACS.

- **Immediate Post-Operative Documentation.** In addition to improving communication through a pre-operative time-out for the surgical team prior to surgery, an important aspect of patient care is to prevent so-called “hand-off” errors by ensuring that those who provide post-operative care have essential information about the patient’s condition. Prompt documentation in a brief post-operative report by the surgeon that includes any specific directives for care can help ensure that the post-operative health care team is prepared for potential complications that may need to be monitored or addressed. This practice fulfills one of JCAHO’s 2006 National Patient Safety Goals across various care settings.
- **Post-Operative Pain Management.** Pain management is an important but sometimes neglected component of a patient’s treatment and important in speeding recovery. Surgeons need to incorporate into their post-operative care processes discussions with their patients about the level of their pain, followed by appropriate pain management. The Centers for Medicare and Medicaid Services (CMS) included pain management in its demonstration project for cancer patients undergoing chemotherapy; in addition, the CMS and AHRQ Hospital CAHPS venture surveys patients regarding the management of pain provided by their hospital.
- **Appropriate Post-Operative Care.** As important as the care the patient receives in the hospital is the care and the directives for care that the patient receives upon discharge. These follow-up steps may include: 1) scheduling post-operative visits with the surgeon or other relevant providers; 2) prescribing medications with the necessary instructions; 3) counseling for particular patient lifestyle choices, such as smoking cessation; 4) directives for patient representatives regarding care for the patient at home; and 5) any other directives appropriate to the patient’s condition, such as wound care.

These measures are broadly applicable across surgical specialties and across sites of services, and should be reportable through relatively straightforward administrative mechanisms. In addition, they are likely to have an immediate positive impact on the quality of care and, taken as a group, will produce little if any increase in service utilization. Indeed, collectively they may well produce system cost savings by preventing complications.

Second Phase

Phase II of Medicare’s pay-for-performance program could call more directly for surgeons to “pay for participation,” and involve targeted goals that rely on more complex process and outcomes measures that are applicable to broad service categories. For surgical care provided in the hospital setting, a widely endorsed set of measures that is applicable to most surgical specialties is incorporated into the Surgical Care Improvement Program (SCIP). SCIP addresses the following surgery-related quality and safety issues:

- **Surgical site infections (SSIs)** account for 14 to 16 percent of all hospital-acquired infections and are a common complication of care, occurring in 2 percent to 5 percent of patients after clean extra-abdominal operations and up to 20 percent of patients undergoing intra-abdominal procedures. Among surgical patients, SSIs account for 40 percent of all hospital acquired infections. By implementing projects to reduce SSIs, hospitals could recognize a savings of \$3,152 and reduction in extended length of stay by seven days on each patient developing an infection. Among the practices known to prevent surgical site infections are timely administration and proper duration of antibiotics, glucose control, and proper hair removal.
- **Adverse cardiac events** are complications of surgery occurring in 2 to 5 percent of patients undergoing non-cardiac surgery and as many as 34 percent of patients undergoing vascular surgery. Certain perioperative cardiac events, such as myocardial infarction, are associated with a mortality rate of 40 to 70 percent per event, prolonged hospitalization, and higher costs. Current studies suggest that appropriately administered beta-blockers reduce perioperative ischemia, especially in patients considered to be at risk. It has been found that nearly half of the fatal cardiac events could be preventable with beta-blocker therapy.

- **Deep vein thrombosis** (DVT) occurs after approximately 25 percent of all major surgical procedures performed without prophylaxis, and **pulmonary embolism** (PE) occurs in 7 percent of operations conducted without prophylaxis. More than 50 percent of major orthopaedic procedures are complicated by DVT, and up to 30 percent by PE, if prophylactic treatment is not instituted. Despite the well-established efficacy and safety of preventive measures, studies show that prophylaxis is often underused or used inappropriately.
- **Postoperative pneumonia** has been associated with high fatality rates, according to the Centers for Disease Control and Prevention (CDC). Postoperative pneumonia occurs in 9–40 percent of patients and has an associated mortality rate of 30–46 percent. Studies have found that many of the factors that can lead to post-operative pneumonia respond favorably to medical intervention and so are preventable. A conservative estimate of the potential savings from reduced hospitalization due to postoperative pneumonia is \$22,000 to \$28,000 per patient per admission. Again, SCIP proposes tests that can be applied to test whether prevention strategies for postoperative pneumonia have been followed.

The SCIP measures were proposed in a partnership that includes CMS, AHRQ, CDC, VA, JCAHO, ACS, and other national organizations representing members of the surgical team.

Employing the SCIP criteria in a pay-for-performance program would involve coordinated efforts with hospitals and with Medicare's quality improvement organizations. Indeed, since hospital adherence to the SCIP protocols depends on surgical leadership, one way to align hospital and physician incentives in the payment system would be to pay "bonuses" to surgeons who refer their patients to hospitals participating in the SCIP.

Of course, because SCIP measures focus on hospital care, other widely-accepted and clinically relevant goals, processes, and measures must be developed that are appropriate for physicians and surgeons whose practice is narrower in scope and those who practice in non-hospital settings. Participation by the relevant professional organizations is key to this effort, as is adequate time for pilot testing and implementation.

Third Phase

Phase III, the most forward reaching effort, would place greater emphasis on the outcomes of surgical care. Such quality initiatives will require large infrastructures to house and analyze data and to provide the professional expertise to define, refine, and report on quality and outcomes. This phase will also involve professional review of outcomes data that, in turn, will produce new performance processes that will further improve care. It may be possible during this stage to benchmark performance of individual surgeons for the purpose of public reporting.

Surgery generally accepts the principle that reporting on outcomes provides the first step in a multi-step process toward quality improvement. Once risk-adjusted outcomes are identified, we can define opportunities for improving care and even highlight areas of exceptional care, and then use expert panels of clinicians to identify the processes that are involved in high-quality care delivery.

Various patient databases can be used to launch this effort, including some developed in the private sector by surgical organizations such as ACS and the Society of Thoracic Surgeons (STS). The National Surgical Quality Improvement Program (NSQIP), developed first by the VA and now under development in the private sector by ACS, as well as the STS National Database for cardiac surgery, hold promise for providing the data and measures needed to identify the processes that improve patient care.

Again, it is important to keep in mind that specialties are in various stages of preparedness in developing and adopting such systems, and this must be accounted for in any pay-for-performance framework that is ultimately adopted. This is particularly true for office-based practices and those in smaller communities where resources are more limited. Further, adequate time for developing and pilot testing new measures and processes is essential, because of the considerable risks associated with implementation of poorly constructed data collection and reporting systems.

For this phase, in particular, the administrative investments will be significant and the potential for Medicare program costs savings outside the physician fee schedule can be substantial. So, alternative means of financing performance awards (e.g., shifting unspent funds from Medicare Part A to Part B, broader allowance of so-called gain-sharing, and so forth) must be developed.

Pay-for-Performance

It will be challenging to produce payment incentives that are fair for all physicians and across specialties and service settings. Nonetheless, surgery generally agrees that a Medicare performance-based payment system should incorporate the following principles:

- The primary goal of pay-for-performance programs must be improving health quality and safety.
- Physician participation in pay-for-performance programs must be voluntary, and a non-punitive audit system should be implemented to ensure the accuracy of data.
- Because of differences across specialties and in the federal government's ability to collect and analyze meaningful data, any Medicare pay-for-performance program must be pilot tested across settings and specialties and phased-in over an appropriate period of time.
- Practicing physicians and their professional organizations must be involved in the design of Medicare pay-for-performance measures and programs.
- Physician performance measures used in Medicare pay-for-performance programs must be evidence-based, broadly accepted, and clinically relevant. The metrics must be fair and balanced across specialties and developed using evidence-based work or consensus panels of expert physicians. They must also be kept current to reflect changes in clinical practice.
- Physician performance data must be fully adjusted for case-mix composition including factors of sample size, age/sex distribution, severity of illness, number of co-morbid conditions, and other features of physician practice and patient population that may influence the results. The program should foster the patient-physician relationship, and must not discourage physicians from treating patients with significant health problems or complications out of fear that they will have a negative influence on quality scores and reimbursement. There also must be a mechanism for exceptions to pay-for-performance compliance metrics for clinical research protocols, and in situations where measures are in conflict with sound clinical judgment.
- Performance measures should be scored against both absolute values and relative improvement in values, as appropriate.
- Medicare must positively reward physician participation in pay-for-performance programs, including physician use of electronic health records and decision support tools. Pay-for-performance programs must also compensate physicians for any administrative burden for collecting and reporting data.
- Pay-for-performance programs must not be budget neutral within the Medicare physician payment system or be subject to artificial Medicare payment volume controls such as the sustainable growth rate mechanism. Pay-for-performance programs should not penalize physicians for factors beyond their control.
- For surgical procedures performed in the hospital setting, the processes that improve care frequently involve a surgeon-led team approach. Many of these processes are directed toward preventing costly complications, reducing length of stay, and avoiding readmissions, which substantially reduce hospital costs covered under Medicare Part A reimbursements. Mechanisms must be established to allow performance awards for physician behaviors in hospital settings that produce cost savings outside the physician fee schedule.
- Physicians must have the ability to review and correct performance data, and those data must remain confidential and not subject to discovery in legal proceedings.

Selma, California 93662
July 20, 2005

Dear Congresswoman Johnson, Congressman Thomas, and Congressman Nunes,

First, please accept my gratitude for your interest in the issue of access to health care for women with breast cancer. **The ability of patients in California (particularly those in rural areas) to find care is inextricably linked to Medicare policy.** I hope that your colleagues share your concern; the stakes for my patients are high.

I am a solo practice general surgeon in rural South Fresno County. *I am the only Spanish-speaking surgeon in a region where over 80% of the population is Hispanic.* As a woman who specializes in the treatment of breast cancer, I have found that

many women, particularly the religious Catholic women I serve, prefer to be treated by a woman for reasons of modesty.

It is incredibly difficult to attract qualified doctors to this area. It is more difficult, still, for the patients with few resources to find the specialists they need. As a surgeon in Selma, California, I am referred patients from as far north as Oakhurst and Coarsegold, and as far south as Earlimart. This is a 70-mile radius around Selma, and these patients travel over an hour for their appointments. There simply aren't enough specialists who accept patients covered by the State's Medi-Cal system, and this has a ripple effect on patients covered by Medicare.

Prior to my establishing my practice in 2003, the only procedure performed locally for the treatment of breast cancer was Mastectomy. Additionally, all breast cancer diagnoses were obtained with *Open Surgical Biopsy*, a procedure performed in the hospital, which necessitates anesthesia and a noticeable scar. Because of my training as a surgical resident, I learned to offer *Breast Conservation*, a set of techniques which allows many women to avoid the pain and disfigurement of losing their breast. Additionally, I perform *Minimally Invasive Biopsies* for the diagnosis of breast abnormalities. Using local anesthetic and advanced technology in my office (including Ultrasound guidance and computerized probes), a woman with a breast lump can be given a diagnosis (whether benign or malignant) with minimal discomfort and a 1/8-inch scar. **Because surgery is not used for diagnosis, the results are available within days of a woman first identifying her breast lump or being told of an abnormal mammogram, and the method is more cost-effective than if a hospital procedure were required.** This is an incredibly stressful time for any woman, and any delay just prolongs her and her family's anxiety.

I brought *Sentinel Lymph Node Biopsy* to my rural hospital. This is another minimally invasive technique for staging breast cancer which **saves many women the pain and complications associated with removal of all of the underarm glands** (which used to be the only way to stage breast cancer, and led to severe permanent arm swelling in a large number of women).

Financially, my practice is failing. The reasons for this are clear below. ***It is likely that in the absence of a change, I will be forced to close my practice and leave the San Joaquin Valley (and probably the State of California) within TWO YEARS.***

The negative consequences for me personally and for my patients will be significant. My husband's family has lived in this area for generations, and we had hoped to spend our lives here. ***My patients will be forced to travel even longer distances for breast cancer diagnosis and treatment, which will cause dangerous delays as they struggle to find doctors who are willing to care for them.***

THE PROBLEMS:

MEDICARE

1. Because of planned reimbursement cuts, the current Medicare system is on a collision course with disaster. **Although physicians in the San Joaquin Valley (as the Centers for Medicare and Medicaid Services call us, "Area 99") are currently the LOWEST reimbursed in the state, we will be hit equally hard by the impending cuts.** Coastal and urban areas, which have fewer difficulties attracting doctors, provide the highest reimbursement rates. The San Joaquin Valley has 25% fewer Primary Care doctors, 50% fewer Specialists and 75% fewer Mental Health providers than the rest of California.

2. ***Without action by Congress, Medicare reimbursement to physicians will be cut an additional 4.3% in 2006 and between 4 and 5% ANNUALLY between 2006 and 2013.*** This despite the fact that for certain surgical procedures, my colleagues who practiced in the 1980s now are reimbursed less than HALF of what they were paid then. For younger doctors like me, we have no cushion to soften the fall. ***We will simply have to stop taking care of patients insured by Medicare or close our practices. IT IS UNACCEPTABLE TO FORCE WOMEN IN THE CENTRAL VALLEY TO UNDERGO UNNECESSARY MASTECTOMIES SIMPLY BECAUSE SURGEONS WHO PERFORM BREAST CONSERVATION CANNOT AFFORD TO PRACTICE HERE. I AM WILLING TO SERVE, BUT I WILL BE PUT OUT OF BUSINESS BY PLANNED REIMBURSEMENT CUTS.***

3. The problem of declining Medicare reimbursement doesn't affect only the elderly. **The vast majority of private health insurance companies base their payments to physicians AS A PERCENTAGE OF MEDICARE REIMBURSEMENT RATES.** So a cut in Medicare cuts payments across the board, making a difficult situation even worse. For those of us who accept Medi-Cal (de-

spite the financial hemorrhage it creates in our practices—in mine, it is the only health coverage for up to 60% of my patients), the problem is multiplied. *The financial viability of my practice, already tenuous, will be gone.*

THE SOLUTIONS:

MEDICARE

1. **SPONSOR OR CO-SPONSOR THE “PRESERVING PATIENT ACCESS TO PHYSICIANS ACT OF 2005.”** Senators Jon Kyl and Debbie Stabenow, and Representatives Clay Shaw and Ben Cardin have introduced this legislation as S. 1081 and H.R. 2356. This legislation will help ensure Medicare payments to **allow Medicare patients continued access to needed surgical services**, and provides an alternative to the upcoming reimbursement cuts that will decimate the Medicare program.

2. **OVERHAUL MEDICARE’S FLAWED “GPCI” FORMULA.** As it stands, the “Geographic Physician Cost Index” is a way of **skewing Medicare payments toward physicians who choose to practice in geographically-desirable areas (such as the Central Coast or San Francisco) and away from those of us in rural areas, including the San Joaquin Valley.** This “unequal pay for equal work” is supposedly based on factors such as physician expenses to practice in a particular area. But it totally ignores facts like the skyrocketing housing costs faced by Valley residents, and the very different patient population whom we serve compared with other parts of the State. **We have TWICE the poverty level, more than THREE TIMES the unemployment rate, and \$14,000 less per year in per capita income than the averages for counties better reimbursed by Medicare.** Our percentage of Medi-Cal patients far exceeds that of our more affluent neighbors.

3. **STUDENT LOAN DEBT FORGIVENESS.** As a surgeon, I spent *thirteen years* training to practice my profession. Although I worked throughout my education and earned scholarships to help relieve the financial burden (like most of us, my family couldn’t provide unlimited resources to send me to school), I incurred nearly **\$200,000** in student loan debt by the end of my five-year residency training. At the age of 35, when most of my friends were well established in their careers, I was just starting. Despite the fact that the only debt my husband and I have is our mortgage (we don’t have expensive habits; I drive a pickup truck and our last vacation was a stay with family in Big Creek, CA), we are struggling to meet my student loan payments and still keep our house. I am willing to serve as a specialist in an area with perpetual physician shortages, where it takes years to recruit even one physician. Perhaps this service has enough value to merit helping with the investment it took to get me here, **so that I may stay and continue my work.**

4. **CONSIDER THE IMPLICATIONS OF VALUE-BASED PURCHASING ON PHYSICIANS IN SOLO AND SMALL PRACTICES.** I would gladly and willingly participate in a program which encourages better health care for patients by rewarding those who provide high quality care. I believe in my ability to provide such care; I would leave my profession if I couldn’t meet the standards which my patients deserve. **But PROVIDING HIGH QUALITY CARE IS A DIFFERENT MATTER THAN DOCUMENTING IT.** As a solo practice rural surgeon, my “bottom line” would be devastated by having to come up with \$15,000 or more for Information Technology in addition to the high overhead I already struggle to pay.

As a solo practice physician, I have ONE employee, and not because I wouldn’t like to hire more. I am the secretary, the bookkeeper, the medical assistant, the receptionist, the cashier, the laboratory manager, the equipment technician, the computer “guy,” and often the housekeeper. Oh, yes . . . I am the surgeon, too. I answer the phones at my office and do my own copying not because I prefer it to being a doctor; it’s a financial necessity to keep my practice viable. Please consider the burden that a complicated, expensive reporting system would place on those of us who want to do good work but are limited in resources and staff to document it.

Thank you, *Muchas Gracias* and *Obrigado* on behalf of my patients. G-d bless you for your interest.

Sincere regards,

Linda Halderman, M.D.
General Surgeon



Statement of Sandi Palumbo, Kern County Medical Society, Bakersfield, California

Madam Chairman Johnson, distinguished Subcommittee members, honorable members of the House Committee on Ways and Means, the Kern County Medical Society (KCMS) appreciates this opportunity to submit comments for the record related to value-based purchasing for physicians under Medicare.

Movement towards a process dependent upon investment in health IT infrastructure that ties increases in physician reimbursement to enhanced outcomes is of concern to Kern County Medical Society and physicians practicing in Kern County and the San Joaquin Valley communities.

Key Concern: Development of risk-adjustment techniques

Taking into consideration the disparities facing both providers and residents of the San Joaquin Valley, of key concern is testimony provided by AMA noting, "Currently, there is no reliable method for risk-adjustment, which has grave consequences for purposes of determining a fair comparison of physician performance, payment and public reporting."

Low health literacy and language barriers add to this concern. The lack of education, low literacy and language barriers compound difficulty related to comprehension of basic medical information. Yet, programs must be implemented to enhance and provide appropriate information to patients to enable them to make educated decisions about their health care needs. It is extremely important that physicians are not penalized for adverse consequences in the case of patients with certain ethnic, racial, socioeconomic or cultural characteristics that make them less or non-compliant.

Exhibit A includes background related to the demographics, socioeconomic indicators, health access barriers and health disparities applicable to our region; providing a better understanding for our concern.

Key Concern: Availability and Cost of Health IT

In the telecommunications arena, government and business—with support from the non-profit sector—have partnered to provide many Americans with quality telecommunication services. However, a closer look reveals a disparity between rural and urban/suburban communities, particularly in regards to highspeed Internet access.

In California's rural areas, specifically in the Central Valley, home to most of the state's fastest growing communities, highspeed Internet access remains limited. In the 21st Century, this lack of access impedes participation in the global economy, as well as educational and health-related opportunities.

In recognition of these issues the Great Valley Center with support from SBC, Surewest Communications, Verizon, Global Valley Networks, Pac-West Telecomm, UC Merced, and the California State Association of Counties, convened a summit on August 25, 2004 to discuss obstacles and opportunities related to rural telecommunications in the Central Valley. The participants included service providers (both large and small), non-profit and community-based organizations, educational institutions, and policymakers.

Exhibit B outlines recommendations developed as a result of the August 25, 2004 Summit.

While the use of IT in physicians' offices potentially can improve quality and reduce costs, implementation is costly because of up-front investments in capital, training and integrating IT systems with existing administrative and clinical processes. The business case for physician implementation of IT to improve health care quality is still being made, since the benefits of lower costs and improved health are uncertain and generally accrue more directly to health plans, employers and patients than to physicians. As a result, many physician practices may be reluctant to introduce IT beyond administrative and management systems that directly affect revenues.

As noted in **Issue Brief No. 89—Limited Information Technology for Patient Care in Physician Offices** by Marie C. Reed and Joy M. Grossman, September 2004, Center for Studying Health System Change:

Practice Size Matters

There is significant variation in the availability of information technology across practice settings. The almost 70 percent of physicians in traditional settings—solo, small groups with up to 50 physicians or practices owned by hospitals—were least likely to be in practices using information technology, with IT adoption rates ranging between 8 percent and 50 percent

Physicians in traditional practice settings less likely to be in practices with IT support for multiple functions. Just 7 percent of physicians in small practices reported having IT support, compared with 20 percent of physicians in large groups and medical schools and more than 50 percent of those in staff/group HMOs. Readier access to capital and administrative support staff, the ability to spread acquisition and implementation costs among more physicians, and active physician leadership may explain why larger practices are more likely to adopt IT to support patient care.

Policy Options

Because barriers to IT adoption appear to be greatest for smaller traditional physician practices, policy makers may need to design policies specifically aimed at these physicians. While some of the approaches to speed IT adoption, particularly those addressing financial barriers, may provide incentives for smaller practices, others are less likely to be successful, especially in the near term.

Programs that focus on performance targets offer only indirect motivation—adopting IT may improve the practice's ability to meet the quality targets. Such quality initiatives are unlikely to address the financial barriers to IT adoption for smaller practices. IT investments typically must be made up-front, while incentive payments from a given quality initiative program are small, accrue incrementally on a per-patient basis, and apply to a limited portion of a practice's patient base. In fact, until major health plans or Medicare offer practices significant financial incentives, quality initiatives are not likely to stimulate substantial IT adoption in smaller practices.

Key Concern: Increased Administrative Burden/Cost

Any value-based purchasing program needs to ensure that physicians are not burdened with additional administrative costs, especially for information technology systems that are needed to participate in the program. Physicians cannot continue to absorb unfunded government mandates, and value-based payments for participation in the program should not be undermined by administrative costs.

Many solo and small group San Joaquin Valley physicians find it increasingly hard to maintain a viable practice while providing appropriate care at low or less than optimal rates of reimbursement for high percentages of patients covered by government-funded programs or lacking coverage and the ability to pay for care. Some solo physicians find it necessary to serve in multiple business capacities related to managing their practice as limited revenue prohibits hiring additional staff. Compounding administrative burdens and costs for these physicians may ultimately force them to relocate their practices to higher reimbursed areas, thereby increasing access problems for areas already disadvantaged by lower numbers of physicians.

Low Federal Expenditure per Capita

As reported in February 2005, preliminary results of a CRS study of the San Joaquin Valley and its counties noted the rate for the San Joaquin Valley was over \$2,000 less per capita than the \$6,814 per capita federal expenditure rate for the United States. Data showed that all San Joaquin Valley counties were less than the per capita rate of spending for the United States as a whole. Most counties were substantially below the national per capita rate of \$6,814, ranging between approximately \$1,200 to \$2,800 per capita less.

Exhibit C, excerpts from the February 5, 2005 Memorandum addressed to San Joaquin Valley Congressional Representatives by Tadlock Cowan, Coordinator, CRS Analyst in Rural and Regional Development Policy Resources, Science, and Industry Division, provides more detail related to low federal expenditure per capita for our region.

Additional Concerns

In addition to the above addressed concerns, we wish to emphasize and echo the following overall factors raised by AMA for consideration as you move forward in developing value-based purchasing legislation for physicians:

- (i) physician practices are vastly different in size and type across the country, and, in stark contrast to hospitals, which are fairly homogenous, one size does not fit all;
- (ii) the number of patients needed to achieve a statistically valid sample size;
- (iii) the desire to keep the data collection burden low, while at the same time maintaining accuracy of the data;
- (iv) level of scientific evidence needed in establishing appropriate measures;
- (v) the ability to trace a performance measure back to one or many physicians involved in a patient's care; and

- (vi) the complexities of distributing payments when multiple physicians are involved in a patient's care, and
- (vii) without violating any fraud and abuse laws and regulations.

We commend Chairman Johnson and House Ways and Means Chairman Bill Thomas for your continued efforts related to the difficult task of addressing flaws associated with the current Medicare physician reimbursement formula and appreciate your interest and understanding of factors impacting this matter. We look forward to a new payment system for physicians that keeps pace with the cost of practicing medicine while enhancing the care provided Medicare beneficiaries.

EXHIBIT A

San Joaquin Valley Socioeconomic & Health Indicators

The San Joaquin Valley is located in the southern portion of the Central California Region and stretches almost 300 miles from just south of Sacramento to north of Los Angeles, bordered on the east and west by the Coastal and Sierra Nevada mountain ranges. The Valley comprises 17% of California's landmass. It is one of the largest rural and agricultural areas in the nation and is also one of the most culturally diverse.

The San Joaquin Valley has grown faster than the rest of the state, and as of the 2000 U.S. Census was home to 3.3 million residents, approximately 10.3% of California's population. The Valley has become more ethnically and linguistically diverse in the 10 years between the 1990 and the 2000 U.S. Census. In comparison to statewide demographics, the residents of the Valley have remained much poorer, with lower educational attainment.

Unemployment has remained high and per capita income low. In contrast, since 1990, California as a whole has seen much greater improvements in areas such as income than has the Valley.

Although the Valley enjoys agricultural riches, many of its residents endure very serious health problems.

The dire health conditions of the residents of the San Joaquin Valley were first documented in 1996 in *Hurting in the Heartland: Access to Care in the San Joaquin Valley*. Eight years later, the report, *Health in the Heartland: The Crisis Continues* was published to provide an update on conditions related to the health status of the residents of the San Joaquin Valley. Data on over 60 health-related indicators was presented for the eight San Joaquin Valley counties (Fresno, Kern, Kings, Madera, Merced, San Joaquin, Stanislaus, and Tulare), comparing them to each other and to California as a whole.

The Valley continues to have high rates of disease, poor community health, and lacks an adequate provider network. The Valley still leads the state in infant mortality, teen births, and late access to prenatal care. Some residents have a harder time than do other Californians in finding care due to lack of health insurance, a scarcity of providers, and language and cultural barriers.

In the Valley, 10.2% of the population does not speak English "well or at all." Much research has documented the adverse impact on access to health care imposed by language barriers. Providers have difficulty communicating with patients and patients have trouble understanding providers, following directions, and obtaining insurance. Policies need to be developed that enable compliance with standards for limited-English-proficient patients, such as certification of interpreters and establishing an adequate delivery and reimbursement system for interpreter services.

Perhaps the biggest challenge to Valley health is the quality of the air. The Valley has some of the worst air quality in the nation, which has severe impacts on the health of residents, the economy of the region, and the overall quality of life.

The data demonstrate that poor health access and health status in San Joaquin Valley exist in the context of communities with high rates of poverty, low educational attainment, a high number of female householder families, and a larger percentage of immigrants and non-English speakers. Although many of the San Joaquin Valley's health issues can potentially be explained by demographics, the economy also has an impact. The Valley's low-wage agricultural industry has left many Valley residents without health insurance and with fewer resources to improve their health. The demand for low-wage labor has fueled the immigration of new residents, mostly from Latin America, to work in the fields. Those who provide health services to these newly arriving workers struggle with limited public resources.

Despite advances in medical care across the state, many Valley residents lack the most basic of services. The rising costs of treatment for chronic disease and continued reliance on state and federal funding in a climate of budgetary deficits will lead to further erosion in the health care delivery system and further economic decline.

If current trends continue, the Valley will be less and less able to adequately care for its needy residents.

ACCESS TO CARE

Access to health care directly affects the well being of the population

Every society requires adequate health care services to screen for and prevent disease, manage chronic conditions, and treat injuries and illness. Access to services that provide primary care, mental health care, and oral health care are essential.

The health care delivery system in the San Joaquin Valley remains inadequate to serve the growing population. Provider shortages, hospital closures, and low reimbursement rates for services continue to plague the Valley. Clinics remain indispensable to the system for providing health care for diverse Valley populations. In the San Joaquin Valley, provider shortages are prevalent across the entire health care workforce, including physicians, dentists, nurses and mental health professionals. The San Joaquin Valley has one of the lowest ratios of physicians to population, whereas coastal, urban areas such as the San Francisco Bay Area have the highest ratios.

Hospitals are also facing severe challenges. Closures, bankruptcies, and the financial deterioration of rural hospitals have affected the acute care delivery system in the San Joaquin Valley. Low reimbursement rates from public and private payers; shortages of nurses, pharmacists, and other personnel; implementation of nurse staffing standards; the burden of updating substandard facilities; the cost of compliance with the 2008 seismic standards; and a lack of capital have all contributed to the declining viability of vulnerable rural hospital facilities.

High rates of uninsured in the San Joaquin Valley

Uninsured Californians are not all the same; they differ widely according to age group, ethnicity, and income, as well as in attitudes towards health insurance and reasons for not having coverage. If they are feeling well, many people do not perceive the need to see their primary care physician. However, many common health conditions do not cause people to have noticeable symptoms until they have had the condition for a number of years. In many cases, if a condition is diagnosed early (e.g. breast cancer and diabetes), treatments can be given that can significantly reduce mortality and morbidity that is otherwise associated with the condition if it is diagnosed after a prolonged period following its onset.

High Poverty Rate

Lack of insurance is not simply restricted to the poor. Approximately 40% of the uninsured in California have a family income level at least twice that of the federal poverty level. Poverty is also a factor for many without sufficient access to health care.

Primary care physician shortages

Primary care physicians play an important role in care. Yet, often there are not enough to treat the population. Medicare reimbursement for San Joaquin Valley physician is among the lowest in the state. Medicare physician reimbursement rates impact upon more than services provided to Medicare beneficiaries as many private carriers use Medicare rates to establish their respective rates applicable to physician reimbursement. In spite of the bonus incentives provided by Medicare by means of primary care health manpower shortage designation or physician scarcity designation, known as having some of the lowest reimbursement rates in California San Joaquin Valley communities experience difficulty in recruiting and retaining an adequate supply of physician providers.

Recent data show that the San Joaquin Valley had approximately 24% fewer primary care physicians and approximately 50% fewer specialists serving Valley residents than the residents of California as a whole. In 2000, there were 51.2 primary care physicians per 100,000 persons in the Valley, compared to 67.4 in California. There were only 73.2 specialists per 100,000 persons in the Valley, compared to 122.2 for California. Areas of shortage of primary care physicians have been designated in every San Joaquin Valley County (See Exhibit D).

Why is this important?

- Primary care physicians are primarily responsible for the prevention, early detection, and treatment of common chronic conditions. These efforts are critical to reducing mortality and morbidity.
- When there is a limited availability of physicians in a community, people are less likely to seek preventive care and more likely to go to a local emergency room or urgent care center for acute symptoms and/or health conditions.

The Rural Health Care Work Environment

While it is generally accepted that the working conditions in the health care field are difficult and often are risk factors for the negative effects of professional quality of life, working in a rural community adds another layer of complexity. The issues faced by any provider may lead to burnout and work-related traumatization. These professional quality of life risk factors, briefly discussed below, are often increased in number and intensity for those working in rural and isolated environments.

Many rural health professionals work as sole providers isolated by geography, distance, weather, and/or time. Often, because of community size, the people they treat are also friends, causing stresses on personal/professional relationships. They are required to be generalists, addressing a wide range of issues, effectively becoming 'mini-specialists' to treat patients' specific conditions. In addition to needing individualized specialty knowledge, the overall frequency of seeing any one condition can be low, making it hard to maintain a broad, current level of knowledge and best practices.

Beyond the typical rural clinical issues, it is difficult for professionals to find training time and funding. Coverage for professional leave is often nonexistent; in addition, time taken for leave is not reimbursed, causing a drop in income. Finally, traveling to access professional education can be hard. Many rural providers must drive one to three hours to reach a community large enough to provide the needed education or access to an airport to fly to a conference. To access continuing education, rural providers can easily lose two productive days of caregiving just in travel alone.

HEALTH STATUS

More seniors living on their own with disabilities in the San Joaquin Valley than in other regions.

The San Joaquin Valley has a higher (worse) level of senior disability when compared to California. Nearly half of non-institutionalized seniors in the San Joaquin Valley live with disabilities. Seniors with disabilities require more specialized care, yet their independence is still very important to their well being. Access to care can be a greater issue for this population compared to seniors without disabilities.

Why is this important?

- People with disabilities tend to report more anxiety, pain, sleeplessness, and days of depression and fewer days of vitality than do people without activity limitations.
- People with disabilities also have other disparities, including lower rates of physical activity and higher rates of obesity.

Valley wide, the rate of coronary heart disease deaths is slightly above that of the state

Many deaths could be prevented because coronary heart disease is related to certain lifestyle-related risk factors. These include high blood pressure, high blood cholesterol, smoking, diabetes, obesity, and physical inactivity—all of which can be controlled.

One in five people without previous symptoms of coronary heart disease die suddenly from an arrhythmia or heart attack. The majority of people go on to live their lives affected by conditions such as shortness of breath, difficulty walking short distances, or difficulty with performing simple activities of daily living (i.e. preparing a meal). These symptoms contribute significantly to disability associated with coronary heart disease.

High incidence of cerebrovascular disease

The Central Valley has the second highest cerebrovascular disease death rate at 67 per 100,000 people when compared to the San Francisco Bay Area (69), California (63), and the Los Angeles Region (61). Within the Central Valley, the San Joaquin Valley (64.5) is slightly higher than the state average (63).

Death rate from diabetes highest in the San Joaquin Valley

Overall, the risk for premature death among people with diabetes is about two times that of people without diabetes.

Hispanic/Latino Americans are almost twice as likely to have diabetes than non-Hispanic whites of similar age.

The San Joaquin Valley has a higher Asthma prevalence rate than the state average

Although asthma affects Americans of all ages, races, and ethnic groups, children, low income, and minority populations are particularly affected. Asthma adversely

affects the quality of life of both the person with asthma and his or her family. It often causes restrictions of many activities in which they participate, many nights of lost sleep, a disruption in daily routines, and is frequently associated with lost days of school and work.

SOCIAL INDICATORS

Unlike the previous measures, social indicators rely primarily on behavioral changes to improve the health of the region. The emotional and related effects of these health-related issues can extend beyond those directly involved, with devastating effects on families and communities.

- Cigarette smoking can lead to numerous health problems, not the least of which is lung cancer. Smoking prevalence is highest in the Valley when compared to other California regions and the state.
- Domestic violence victims are most often women. The Valley is just above the state rate for both hospitalizations and homicides due to domestic violence.
- Long-term heavy drinking can lead to heart disease, cancer, alcohol-related liver disease, and pancreatitis. Aside from the effects that heavy alcohol use has on the body, it is also associated with abuse of loved ones, sexually transmitted diseases, and other social problems. Heavy alcohol use and alcohol abuse is strongly associated with motor vehicle accidents, homicides, suicides, and drowning. The Valley rate for alcohol abuse is higher than the California rate.
- Drug abuse in the San Joaquin Valley, where drug-related misdemeanor convictions exceed that of all Central Valley sub-regions, is higher than in other regions in the state.

EXHIBIT B

Great Valley Rural Telecommunications Summit

Rural Highspeed Access—Obstacles & Opportunities

Designing Regulatory, Economic, and Policy Recommendations for Rural Highspeed Access

August 25, 2004—Sacramento, California

Conclusion/Recommendations

As published in the position paper providing a summary of the Summit, recommendations can be grouped into the following areas identified for improvement:

- 1) Easing the process of extending communications infrastructure into rural areas by providing tax credits to providers, expediting the approval process for use of rights-of-way and permit requests, encouraging appropriate building and zoning codes, and creating an investment climate that is attractive to Internet service providers.
- 2) Addressing the issue of unused bandwidth in rural areas through spectrum reform and anchor tenancy. These concepts capitalize on existing broadband infrastructure not being used to its capacity and have the potential to lower costs and speed deployment to rural areas.
- 3) Developing a comprehensive policy on broadband use in rural areas which assures residents, providers, and investors of the State's commitment to providing broadband access to all residents.
- 4) Increasing and improving funding for communications infrastructure, education and training available through both state and federal channels.

Summit participants believe, by making changes in these areas, steps can be made toward achieving greater parity in highspeed access between rural and urban/suburban communities, which will have positive effects on participation in the global economy, as well as access to educational and health-related opportunities.

Summit Participants

Sharon Avery, California Telemedicine and eHealth Center
 Gretchen Beyer, Technology Network (TechNet)
 Lisa Bickford, InReach Internet
 Keith Boggs, County of Stanislaus
 Merita Callaway, CA State Association of Counties
 Carol Chamberlain, Prosper Magazine
 Mark Cowart, County of Kings
 Mark Crase, CA State University Long Beach

MaryLiz DeJong, SBC
 Ron Dibelka, National Exchange Carriers Association
 Jim Dolgonas, Corporation for Education Network Initiatives
 Thomas Dorr, U.S. Department of Agriculture
 Joel Effron, Pac-West Telecomm
 Patrick Enright, Kronick Moskovitz
 Seth Fearey, Joint Venture Silicon Valley Network
 Margaret Felts, California Telephone Association
 Douglas Garrett, Cox Communications
 Susan Gonzales, Comcast
 James Gordon, Communications Workers of America
 Kathy Halsey, SBC
 Allen Hammond, Santa Clara University School of Law
 Peter Hayes, SBC
 Yvette Hogue, SBC
 Sheila Hurst, Great Valley Center
 Sue Hutchinson, Global Valley Networks
 Richard Jantz, County of Stanislaus
 Stuart Jeffery, Wireless Communication Alliance
 Eric Johnson, SBC
 Barbara Johnston, California Telemedicine and eHealth Center
 Susan Kennedy, CA Public Utilities Commission
 Ross LaJeunesse, CA Public Utilities Commission
 Pat Lanthier, *Rivera Lanthier & Associates*
 Sarah Lapachet, Congressman Richard Pombo
 Lesla Lehtonen, *California Cable & Telecommunications Association*
 Scott Lindsay, Rural Broadband Coalition
 Carolyn Lott, Great Valley Center
 Mike Lynch, Great Valley Center
 Jamie Malone, SBC
 Timothy McCallion, Verizon
 Camden McEfee, California Strategies
 Bill Moreno, Fire2Wire
 Baldwin Moy, California Rural Legal Assistance
 Stephen Myers, Sacramento ACORN Del Paso Chapter
 Dan Nguyen, CA State University Sacramento
 Barbara O'Connor, CA State University Sacramento
 Ted Olson, OACYS Technology
 Colin Patheram, SBC
 Robert Pepper, Federal Communications Commission
 Bob Pickard, County of Mariposa
 Daniel Roix, Great Valley Center
 Duane Severson, Fire2Wire
 John Sumpter, Pac-West Telecomm
 Don Vial California, Foundation on Environment & Economy
 Loretta Walker, SBC
 Mark Welch, SBC
 Carol Whiteside, Great Valley Center
 Jeff Williams, California State Association of Counties
 Ileana Winterhalter, SBC

EXHIBIT C

Excerpts: February 5, 2005 Memorandum to San Joaquin Valley Congressional Representatives
by Tadlock Cowan, Coordinator
CRS Analyst in Rural and Regional Development Policy Resources, Science, and Industry Division

San Joaquin Valley vs. the United States: Per capita federal direct expenditures and obligations to the San Joaquin Valley were \$4,736 for FY2002. The rate for the San Joaquin Valley was over \$2000 less per capita than the \$6,814 per capita federal expenditure rate for the United States. Data showed that all San Joaquin Valley counties were less than the per capita rate of spending for the United States as a whole. Most counties were substantially below the national per capita rate of \$6,814, ranging between approximately \$1,200 to \$2,800 per capita less.

San Joaquin Valley vs. California: All San Joaquin Valley counties had a lower rate than the direct federal expenditures and obligations rate of California, although the gap was somewhat less than that between the San Joaquin Valley and

the United States. California's per capita rate of federal direct expenditures (\$6,094) was also lower than that of the United States. With the exception of the category of federal salary and wages in two counties, all San

Joaquin Valley counties had a per capita federal expenditure level below the national per capita rate in all of the established categories of federal spending (retirement and disability, other direct payments to individuals and others, grants, procurement contracts, and salaries and wages). The per capita rates of federal spending for most San Joaquin counties for each category were also lower than California's per capita rates.

Metro vs Non-metro: With the exception of Kings County, the 8 counties comprising the San Joaquin Valley are metro counties as defined by the U.S. Bureau of the Census. Metro counties in the United States, on average, receive higher per capita federal expenditure rates than the national rate. This was not the case in the San Joaquin Valley. Kern County had the highest per capita rate of direct federal expenditures (\$5,667) followed by Kings County (\$5,550), a non-metro county. Kern County had the second largest 2000 population after Fresno County while Kings County had the second lowest population in the San Joaquin Valley.

San Joaquin Valley vs. the ARC Area: In 2002, the San Joaquin Valley received \$1,295 per capita less (21%) than the Appalachian Regional Commission region in direct federal expenditures and obligations. The ARC region received \$783 less than the national per capita rate while the San Joaquin Valley received \$2,078 less than the national per capita rate. Only 6 of the 13 ARC state Appalachian regions, however, matched or exceeded the ARC region's per capita rate. Individual ARC counties within the 13 states that comprise the ARC region may also receive lower per capita rates than their respective state rates. In only one state's ARC counties (Georgia) was the per capita rate of direct federal expenditures lower than that of the San Joaquin Valley.

Adjacent County Comparison: Two rural counties adjacent to the San Joaquin Valley, Mariposa and Tuolumne, received higher direct federal expenditures and obligations per capita in 2002 than did the San Joaquin Valley. Per capita rates for these two counties, however, were also lower than the national per capita rates, and Tuolumne County's per capita rate was lower than the state's per capita rate.

Population Growth in the San Joaquin: The San Joaquin Valley has experienced significantly higher population growth rates between 1990 and 2003 than California or the United States (30.6% vs. 19.2% and 16.9% respectively).

Total county federal expenditures to the San Joaquin for 2003, based on 2003 population figures, show that the same general patterns as noted above persist. Although the per capita federal expenditure rates for some San Joaquin Valley counties in 2003 were somewhat higher than in 2002, they were still lower relative to the 2003 per capita rates of the United States and California. For the Valley as a whole, however, the per capita rate fell \$117 in 2003 while the population grew by approximately 280,000.

Madera County: Madera County, which had one of the 10 lowest per capita income levels for any metropolitan area in the United States in 2002, had a per capita decrease in federal expenditures of approximately \$150 in 2003 compared to 2002. At the same time, the population of the county grew by over 10,000 (8.4%) between 2000 and 2003. Madera also had the highest population growth rate in the San Joaquin Valley between 1990 and 2003 (51.5%) and between 1980 and 1990 (39.6%). Population growth in the San Joaquin Valley is projected to grow by over twice the national rate between 2003 and 2020 and, in some counties, by over three times the national average between 2003 and 2020. In contrast, growth in the adjacent counties of Mariposa and Tuolumne is projected to grow at about the national average between 2003 and 2020 and less than the California average.

Socioeconomic Characteristics of the San Joaquin Valley

Population: The San Joaquin Valley population is growing rapidly. Each of the San Joaquin Valley counties exceeded the national rate of population growth between 1980–1990, 1990–2000, and 1990–2003. While California has also had relatively higher growth rates than the national average, each San Joaquin Valley county substantially outpaced the growth of California in the previous two decades. The adjacent counties of Mariposa and Tuolumne have also had generally higher growth rates than either California or the United States over the past 2 decades. San Joaquin and Stanislaus counties now have population densities considerably higher than the California average. With the high proportion of federal land in Mariposa and Tuolumne, these counties have had relatively stable population densities.

Population Projections: In addition to documenting population changes over time, the U.S. Bureau of the Census also makes population projections. The San

Joaquin Valley population is projected to grow by 14.3% between 2003 and 2010 compared to projected growth rates of 10.6% for California and 6.2% for the United States. Projected population growth for the San Joaquin Valley between 2003 and 2020 is 39.0% compared to a growth rate of 15.5% for the United States and 23.6% for California. Population growth between 2003–2020 for Mariposa and Tuolumne counties is projected to be about the same as the national average but less than California.

Poverty and Income: Socioeconomic conditions in the San Joaquin Valley as measured by a range of variables including per capita income, poverty and unemployment rates, and median household income reveal an area that falls significantly below national and California averages. The 2000 poverty rate for the San Joaquin Valley (20.5%), for example, was significantly higher than the national rate (12.4%), California (14.2%), and the Appalachian Regional Commission area (13.6%). While the Valley's poverty rate was somewhat closer both to the national and California averages in the 1980s, during the 1990s, the San Joaquin counties saw significant increases in their poverty rates. All San Joaquin Valley counties were below the 2000 national median family income level (\$50,046) or that of California (\$53,025). With the exception of Stanislaus and San Joaquin counties, the Valley's counties were substantially below these national and California median family levels. The two adjacent counties (Mariposa and Tuolumne) had 2000 poverty rates of 14.8% and 12.4% respectively, although their median family income levels were lower than both California's and the national rate. In contrast, poverty rates for the ARC region, 1980–2000 were significantly lower than those of the San Joaquin counties, although 4 Social data tables prepared by Gerald Mayer, Analyst in Public Finance that of some Appalachian states was comparable to the Valley. ARC rates were slightly greater than the United States during those decades, although ARC poverty rates did vary by state.

Immigration: Immigration plays a significant role in the demographic characteristics of the San Joaquin Valley and California, and this is likely to continue. Since 1995, the Central Valley as a whole has received substantially more migrants from other parts of California than they send to the rest of California. The counties of Madera, Fresno, Kings, Tulare, and Kern have received the most international migrants of any area of the Central Valley. These counties are economically dominated by industrial agriculture and they also are characterized by high rates of poverty among immigrants, who also have generally low education levels and limited English language skills. These characteristics present challenges to the region's social services, especially health and education providers.

Statement of Cherrill Farnsworth, National Coalition for Quality Diagnostic Imaging Services

Chairwoman Johnson, we are pleased to have this opportunity to provide testimony for the record to the House Ways and Means Subcommittee on Health at a hearing on "Value-Based Purchasing for Physicians under Medicare." NCQDIS is comprised of more than 2,400 outpatient imaging centers and departments in the United States. The coalition promotes "best industry practices," strategies for healthcare cost savings and advocates for public and private sector standards for quality and safety in diagnostic imaging services.

Advances in diagnostic imaging have led to great strides in patient care: from reducing the need for invasive surgical procedures to early detection of life-threatening diseases. NCQDIS and its members are at the forefront of medical technology, providing physicians and patients with the most state-of-the-art innovations, techniques and procedures available in diagnostic imaging.

We are pleased to have this opportunity to comment to the House Ways and Means Subcommittee on Health on efforts to promote delivery of quality health care services and tie physician payments to quality performance. We believe that implementing quality standards for diagnostic imaging services is central to addressing quality issues in the Medicare program. Medicare currently pays the same amount for imaging services regardless of the quality of the service performed. Medicare payment does not take into account the quality of the imaging equipment used, the skill level of the technician facilitating the test, or the physician's proficiency in interpreting the images. In essence, Medicare pays the same amount for a test conducted on state-of-the-art imaging equipment by a world-renowned radiologist as it does for an untrained physician conducting a test on obsolete diagnostic imaging equipment. The cost of diagnostic imaging to the Medicare program is significant.

Imaging services accounted for over \$10.1 billion in Medicare Part B allowed charges in 2003, and implementing quality standards for complex diagnostic imaging services would result in Medicare savings in the range of \$1.6—\$4.8 billion over 10 years.

As you can see, diagnostic imaging is one of the most obvious areas in which tying quality standards to payment for services can almost immediately increase the quality and safety of services provided to Medicare patients and maximize Medicare dollars for services rendered. NCQDIS is actively promoting legislative options that would increase the quality of care to Medicare patients while addressing the committee's cost concerns about the physician payment system. Today, many of the policies and standards supported by NCQDIS have been implemented by private payers to successfully reduce costs and improve patient safety and quality. The coalition believes that the same policies and programs that are working in the private sector should be available to protect Medicare beneficiaries and safeguard the Medicare Trust Fund.

Protecting Beneficiaries And The Trust Fund Requires Medicare Take A Closer Look At Use Of Imaging

As you know, data from MedPAC and the GAO have raised concerns about the growth of diagnostic imaging performed by non-radiologists. MedPAC found that imaging services increased by 9% between 1999 and 2002.¹ Other research has defined the growth in imaging services between 1993–2002 as 49% by non-radiologists. Interestingly, services provided by radiologists who typically have no incentive to self-refer have grown only by 7%. In addition, the growth in Medicare payments for radiology services grew by 72% for radiologists and by 119% for non-radiologists.²

Medicare Should Incorporate The Innovations Of The Private Sector

Empirical evidence demonstrates that private sector management strategies promote high quality care. For example, Tufts Health Plan uses an Imaging Privileging Program to address quality and utilization issues for non-emergency, outpatient diagnostic imaging provided by non-radiologists. Services are covered when providers meet standards to perform specialty-appropriate imaging procedures; otherwise, imaging procedures must be provided by a radiologist or imaging facility. Miriam Sullivan, representing Tufts Health Plan, has testified to MedPAC that by expanding the use of freestanding imaging facilities and increasing competition, physician groups have less desire to purchase equipment and more incentives to use Tufts' quality and evidence-based guidelines.³

We firmly believe that private sector quality standards should also be available to Medicare beneficiaries. Highmark uses guidelines where imaging facilities must have a documented Quality Control Program, Radiation Safety Program, and As Low As Reasonably Achievable (ALARA) Program. Highmark providers must be appropriately licensed and meet the physician specialty criteria in the plan's privileging guidelines.⁴

States have also become concerned payers of diagnostic imaging services and are increasingly taking action at the state level to limit physician self-referral of services. The State of Maryland passed legislation in 2000 that is similar to the federal Stark ban on physician self-referral, except that § 1–301(k)(2) of the law specifically excludes magnetic resonance imaging services, radiation therapy services, and computer tomography scan services from the in-office ancillary services exception. The Maryland Attorney General released a legal opinion on January 5, 2004, stating that this law bars a non-radiologist physician from referring patients for tests on an MRI machine or CT scanner owned by that practice. Medicare should have the same opportunities to increase quality and contain unnecessary utilization that are being implemented at the state level.

Medicare Beneficiaries Should Be Assured Of Access To The Highest Quality Imaging Services

Like private payors, Medicare should only pay for imaging services that meet quality standards. Medical literature shows that imaging equipment and facilities operated by non-radiologists is often sub-optimal. One private sector imaging site inspection program revealed that over 1/3 of imaging facilities operated by non-radiologist physicians had one or more significant quality deficiencies, while only 1% of

¹ Report to the Congress: Medicare Payment Policy, MedPAC, March 2003, page 77.

² Levin DC, Intenzo CM, Rao VM, Frangos AJ, Parker L, Sunshine JH. Comparison of recent utilization trends in radionuclide myocardial perfusion imaging among radiologists and cardiologists. *J Am Coll Radiol*, in press.

³ Medicare Payment Advisory Commission, Meeting Transcript, March 18–19, 2004, page 53

⁴ http://icael.org/icael/reimbursement/highmark_press.htm

facilities operated by radiologists had such deficiencies.⁵ Quality standards for equipment and facilities would reduce the need for duplicate scans or expensive therapy from incomplete images or misdiagnosis.

We are especially concerned that non-radiologists' offices are less likely to become accredited. Though the ACR has full accreditation programs for many diagnostic procedures, non-radiologist physician offices are not required to become accredited to provide these services. ACR began an MRI accreditation program in 1997, including standards for equipment and for qualifications of technologists performing the test. Though non-radiologists may voluntarily become accredited, most do not. Almost all accredited entities are freestanding MRI centers owned by radiologists or hospitals, or are contracted with radiologists. NCQDIS believes that all physician offices providing imaging services should be accredited.

In addition, the recycling of obsolete diagnostic imaging equipment should be curtailed by implementing strong equipment standards. Dr. Thomas Ruane, BC/BS of Michigan, testified to MedPAC that, "The diagnostic equipment that becomes somewhat obsolete in our tertiary medical centers often does not go to the Third World. It often goes down the street to another doctor's office where it lives another life."⁶ NCQDIS believes that Medicare patients deserve better.

NCQDIS Promotes The Appropriate Use Of Diagnostic Imaging By Trained Specialists

Proper training is essential to accurate interpretation of diagnostic images, particularly when dealing with complex diagnostic imaging procedures like MRI, CT, and PET. Radiologists spend 4–6 years in residency training to learn imaging techniques and interpretation. Physicians in other specialties get limited amounts of training in certain areas of imaging; however, sometimes that training may be informal and may not meet defined standards. Most troubling is that many non-radiologist physicians utilizing diagnostic imaging have limited or no formal training in image interpretation. To protect patient safety and reduce medical errors, Medicare should only reimburse for imaging services conducted by physicians that meet certain training and education standards.

Evidence also demonstrates that quality of care is improved if properly trained specialists read diagnostic images. In 2000, one research group used a standardized set of chest radiographs to compare the accuracy of interpretation of radiologists and non-radiologists. The composite group of board-certified radiologists demonstrated performance far superior to that of non-radiologist physicians. Even radiology residents in training out-performed non-radiologist physicians.⁷

It should be noted that radiologists and IDTFs serve an important role in providing quality diagnostic services to patients and practitioners. Radiologists working with other clinicians provide an important second opinion in clinical diagnosis, helping to minimize medical errors. Radiologists also serve as an important second opinion in clinical diagnosis, treatment, and management of patients needing diagnostic imaging services. IDTFs serve a similar role in patient treatment, and imaging centers owned by radiologists and IDTFs do not create any artificial demand for imaging services. Business is independently referred to imaging centers from third party physicians who determine that a patient needs a diagnostic imaging test. Therefore, radiologists and IDTFs are limited in their ability to generate business outside of that which is referred.

NCQDIS Recommends That Medicare Take Steps Now to Protect Medicare Beneficiaries

NCQDIS is pleased to submit its recommendations to the House Ways and Means Subcommittee on Health on the best way to promote quality of care in diagnostic imaging. Congress has the opportunity to act now to address this important issue and protect Medicare beneficiaries.

1. Congress should expand the term "diagnostic services" under the definition of "medical and other health services" to create a separate category of diagnostic services, called "complex diagnostic imaging services." This term would statutorily include include particular procedures (at a minimum: computed tomography, magnetic resonance, positron emission tomography) that must be "furnished by or under the supervision of a physician in compliance with qualification criteria" that include educational certification for physicians and technicians and quality and safety requirements. This provision makes "complex di-

⁵ Orrison & Levin, *Radiology* 2002; 225(P):550

⁶ Medicare Payment Advisory Commission, Meeting Transcript, March 18–19, 2004, page 34.

⁷ Potchen, *RADIOLOGY* 2000; 217:456.

agnostic imaging services” a covered “medical and health service” *only* when the additional conditions are met.

2. Congress should then require the Secretary to establish qualification criteria for the provision of complex diagnostic services that include: (1) quality measures for diagnostic imaging equipment; (2) education and certification requirements for technicians; and (3) education and certification requirements for physicians. This provision will require that any party seeking reimbursement for complex diagnostic services will have to comply with the quality and safety standards as developed by the Secretary. Physicians and practitioners that do not meet these standards cannot be reimbursed through Medicare for the complex diagnostic imaging services provided.
3. NCQDIS also suggests that legislation create a “phase-in” period between enactment of the new definition of “complex diagnostic imaging services” and publication of a final rule establishing the quality standards required by the Act. This provision will allow radiologists to continue to perform these services while the Secretary conducts the appropriate rulemaking to establish education and quality standards for other appropriately trained specialists.
4. NCQDIS supports updating payment billing systems to align with changes in technology.
5. Finally, NCQDIS understands that implementing quality standards for additional diagnostic imaging services will take a significant amount of time to develop. Therefore, NCQDIS recommends that Medicare be authorized to implement a broader quality standards program through a demonstration project to be implemented one year from the date of enactment of the complex diagnostic imaging quality standards. This policy should detail by medical specialty those imaging tests permitted by the specialty.

The framework of the NCQDIS proposal directly parallels the existing quality requirements embodied in the Medicare statute for coverage of mammograms. The definition of “diagnostic services” mentioned above also establishes that Medicare Part B covers diagnostic x-ray tests including *diagnostic mammography if conducted by a facility that has a certificate* under the Public Health Service Act. The regulations accompanying that Act require interpreting physicians and technicians to (1) engage in extensive education and training, and (2) use equipment that meets stringent quality standards in order to receive and maintain a certificate to furnish mammograms. Hence, Medicare pays for mammograms only if the provider or supplier is certified by the FDA to perform the types of mammography for which payment is sought and uses properly maintained and certified equipment. The NCQDIS proposal described above simply attaches similar education and quality standards to “complex diagnostic imaging services.” This approach will improve quality, protect Medicare beneficiaries, and safeguard precious Medicare Trust Fund dollars.

Again, we appreciate this opportunity to present our views to the House Ways and Means Subcommittee on Health. We would be pleased to provide the Subcommittee with additional details about our proposal, and to discuss any views and concerns that may be raised with regard to it.

